

■ **Blood-Gas-Electrolyte-Analyser**

■ **For In-Vitro-Diagnostic Use**



Service Manual

IVD

CE

■ **Eschweiler GmbH & Co. KG**

Development - Manufacturing - Sales - Technical Service

Made in Germany

Manual Version

The latest Manual version is: 4.01

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Manual History

Manual Version	ANALYSER-Software Version	Revision Date
4.01	2500	April 2010

Software Copyrights

The software for the *combiLine* Analyser is the User and Instrument Control Software for the *combiLine*. The *combiLine* Software is the intellectual property of Eschweiler GmbH & Co. KG hereafter Eschweiler. Intellectual property rights shall remain with Eschweiler.

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Consumable solutions and spare parts from other manufacturers used in ESCHWEILER Analysers.

We point out specifically that fault-free operation of our analysers can be guaranteed only when original **ESCHWEILER** solutions and spare parts are used.

The name **ESCHWEILER** with its decades of experience in the field of blood gas analysis also stands for the quality of the spare parts and consumable solutions. **ESCHWEILER** sensors and solutions form a functional unit whose components are optimally adapted to each other. Measuring accuracy and long life of the sensors are the goal of this system.

Through intensive development work, the chemical compositions of our solutions have been adjusted optimally to the **ESCHWEILER** sensors and guarantee, besides precise measurements, the greatest possible protection of the sensitive sensor surfaces.

For example, special wetting solutions are used which have a decisive influence on the unconstrained contact between sensor and solution in the measuring capillary. At the same time suitable preservatives prevent the growth of micro-organisms in the consumable solutions and keep them from being introduced into the measuring capillaries of the **ESCHWEILER** analysers.

The characteristics and concentrations of both the wetting- and the preservative substances are selected according to the special requirements of our sensors.

Fault-free operation of our analysers with measuring accuracy and long sensor life are the main goals of our quality requirements. Only if **ESCHWEILER** original parts and solutions are used we can meet these requirements.

Please support us in doing this!

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Safety Issues

Please read the Instruction Manual in its entirety prior to operating the **combiLine**. In order to ensure a high level of performance, all warnings and references to technical safety in this Instruction Manual have to be followed.

! 1 Hazards and Precautions

The cautions and safety regulations in this Instruction Manual meet international classifications:

Warns of a risk of injury or of a risk to life (for example by electrical shock).



Warns of a risk of injury or of the analyser being severely damaged.



Warns of a risk of biological material like blood or other human or animal specimen. Risk of infection! Potential infectious area/material!



Introduces rules to be observed.



The following safety issues have to be observed at all times:

Electrical safety



- Check that **the operating voltage is set correctly** before you connect the device to the main power supply.
- To connect the analyser to the main power supply, use only sockets which are **grounded** to avoid the risk of an electrical shock.
- Use only **grounded** extension power cords. The used power cord has to correspond to the **country specific regulations**.
- **Never** intentionally **disconnect** the grounding contacts.
There is the risk of electrical shock if the protective conductor is interrupted within or outside the analyser, and/or the grounded contacts have been disconnected from the line.
- **Never** remove protective guards or secured components since you could expose electrically live parts in this way.
- Electrical connection contacts (plugs, sockets, etc.) can be electrically live.

Safety Issues

- Even after an analyser has been switched off, components (e.g. capacitors) can be under voltage as the result of an electrical charge.
- All current carrying parts are sources of danger for an electrical shock.
- Surfaces (floors, work tables) have not to be moist when you are working with any electrical device.
- Carry out **only** the maintenance work and/or the replacement of parts described in these Instruction Manual.
- Unauthorized work on the analyser can lead to the guarantee obligation becoming null and void with necessary expensive service work to correct it.
- All work, which requires the analyser to be opened, **have to be carried out by an authorised technician** who is familiar with the risks related thereto.
- Use **only replacement fuses** of the stated type and with the stated nominal current. Never use fuses, which have been "repaired".
- There is a **Lithium battery** on MAIN BOARD **that have to be replaced by the authorised technical service every 5 years!** In case of a battery fault, all memorised parameter might be lost.

Mechanical Safety (Analyser is operating)



- Never open or unscrew analyser's casing parts while it is switched ON. There is a risk of injury due to moving parts as fans, pumps, stepper-motors or any other mechanical movements.

Biological Material - Risk of Infection



- Wear gloves in all cases if there is a risk of infection.
- Avoid any direct contact with samples that are potentially infectious or which may generate other risks to the human body (**Aids, Hepatitis** etc). In case of direct body contact go and wash the contaminated area immediately. Use a suitable skin disinfection solution. Ask your doctor for aid.
- If sample material (blood) or reagent is spilled onto the analyser, wipe it off immediately and refer to the chapter **! 2 Maintenance and Hygiene**.
- Do not open a waste bottle as long as the analyser is in process.

Safety Issues

Reagents and Controls



- Observe the suggestions in the package inserts for an exact use of the reagents and quality controls. Note that reagents and quality control material can be biological material!
- Don't use Reagents, Controls and other Liquids after expiration date!
- Avoid any liquid penetration into the analyser.

Restrictions for Samples, Reagents and Controls



- For consumables no guarantee can be provided for any resistance against organic solvents. For this reason, do not use any organic solvents unless such solvents are expressly indicated.
- Do not use any other rinsing or cleaning solutions as recommended by the manufacturer or representative.
- Waste liquid has to be disposed in compliance with the legislation.

Accuracy and Precision of the Measured Results



- In order to ensure a flawless operation of the analyser measure control samples and watch the function of the analyser closely.
- Faulty measurement results may result in an incorrect diagnosis or range danger for patient.

Fire and Explosion Hazards



- Do not place any flammable or hazardous explosive material in the proximity of the device. Electrical sparks could cause fire or explosions.

Operator Qualification

- The analyser **should only be operated** by trained personnel. Improper operation of the analyser might cause inaccurate measuring results!

! 2 Maintenance and Hygiene



- No **organic acid** based cleaning substances should be applied. Instead use cleaner designed for cleaning and disinfecting laboratory analysers. **Only use** a dampened cloth to clean the analyser.
- **Never spray** or pour cleaning solution directly onto the analyser, that may negatively impact the analyser's functions significantly.
- Keep the analyser clean and **do not spill liquids** onto it.
- In case liquids were spilled onto the analyser, immediately absorb liquid with a suitable cloth.
- Contact your distributor if your control measurements do not produce the expected results.

Safety Issues

Recommended Disinfectant Solutions.

A suitable disinfectant is available by BODE Chemie, Hamburg: **Bacillo®**, is recommended for areas at risk of infection, where **rapid contact times and drying times are necessary**.

BODE Chemie GmbH & Co
Melachtonstr. 27 - 22525 Hamburg, Germany

Phone: +49- (0)40-54 00 60 - Internet: www.bode-chemie.de

Another suitable disinfectant is available by S&M Schülke & Mayr: **TERRALIN® Liquid**

Schülke & Mayr GmbH
Robert-Koch-Str. 2 - 22851 Norderstedt, Germany

Phone: + 49- (0)40-521 00-0 - Internet: www.schuelke-mayr.com

See the website for your nearest representation. Ask for an EC Material Safety Data Sheet according to EC 91/155.

! 3 First-Aid Measures

If a person swallowed any chemical solution may be while servicing, wash out mouth with water.

If provided person is unconscious, **than call a physician**.

If inhaled, remove to fresh air. If breathing becomes difficult, **than call a physician**.

In case of contact, immediately wash skin with soap and copious amount of water.

In case of contact with eyes, flush with copious amounts of water for at least 15 minutes.

Assure adequate flushing by separating the eyelids with fingers, **than call a physician**.

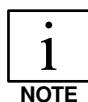
! 4 Repairs



- Repairs to the analyser may only be carried out by trained personnel, and replacement parts have to comply with the analyser specifications.

- In case of analyser problems contact your representative.

Useful hint



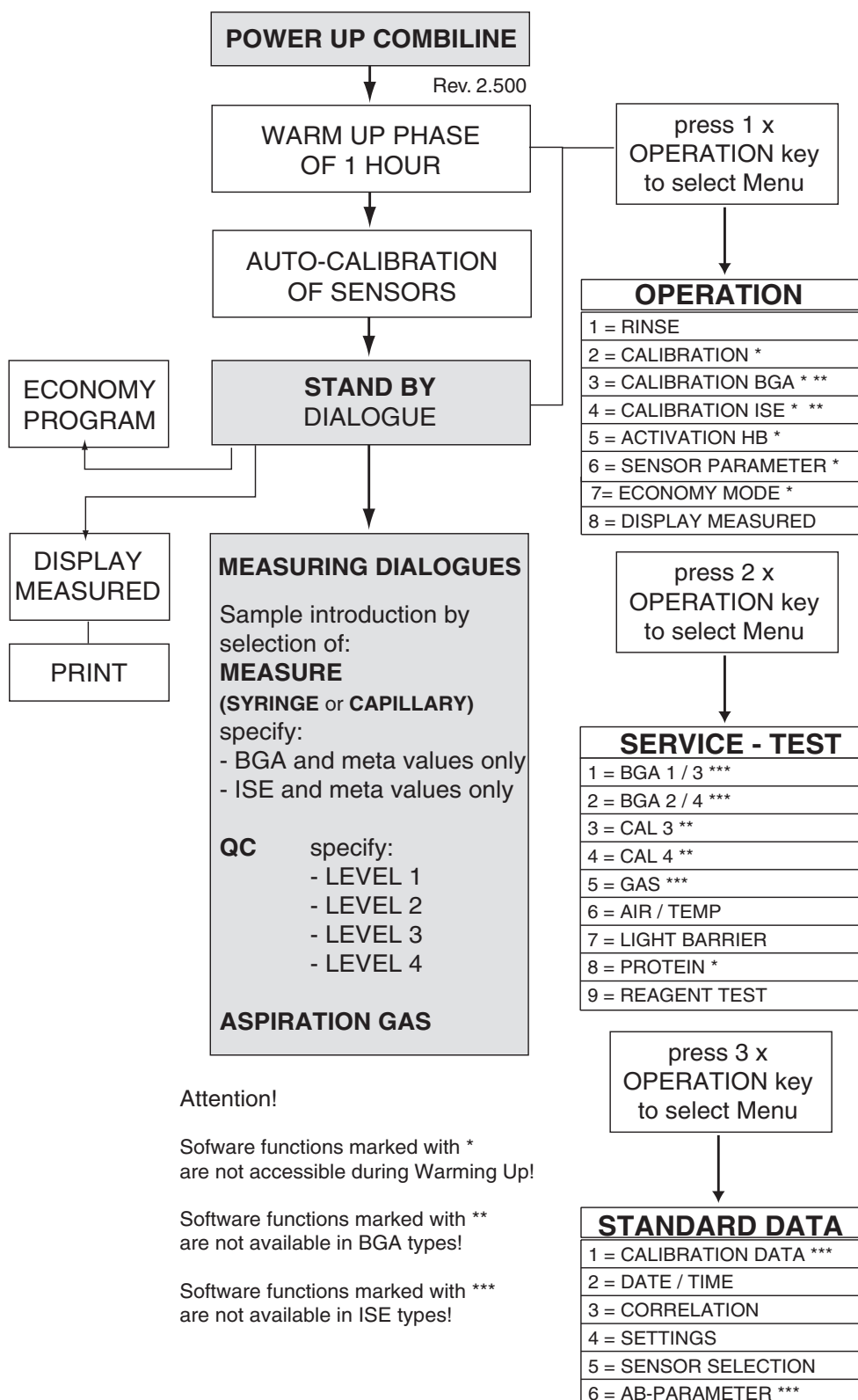
In this Manual a bullet "•" draws your attention to an instruction. Example:

• Press enter-key to confirm ...

Technical Data

Technical Data

measured parameter	range	resolution
pO ₂	0 - 800 mmHg (SI-units selctable)	0,1 mmHg
pCO ₂	5 - 200 mmHg (SI-units selctable)	0,1 mmHg
pH	6,000 - 8,000	0,001 pH
total-hemoglobin (tHb)	3 - 30 g/dl	0,1 g/dl
barometric pressure	500 - 900 mmHg (SI-units selctable)	1,0 mmHg
Na ⁺	20 - 250 mmol/l	0,1 mmol/l
K ⁺	0 - 20 mmol/l	0,1 mmol/l
Ca ⁺	0 - 5,0 mmol/l	0,01 mmol/l
Li ⁺	0,4 - 5,0 mmol/l	0,01 mmol/l
Cl ⁻	20 - 250 mmol/l	1,0 mmol/l
glucose	0 - 30 mmol/l	0,1 mmol/l
lactate	0 - 20 mmol/l	0,1 mmol/l
input parameter		
patient temperature	13° - 43° C	0,1° C
hemoglobin (tHb)	0 - 30 g/dl (if not measured)	0,1 g/dl
fraction of inspired oxygen (FIO ₂)	15 - 100 %	only relevant for AaDO ₂
respiratory quotient (RQ)	0,7 - 1,0	only relevant for AaDO ₂
calculated parameter		
hydrogen ion conc. (H ⁺)	10 - 1000	0,1 nmol/l
actual bicarbonate (HCO ₃ -A)	10 - 50	0,1 mmol/l
standard bicarbonate (HCO ₃ -S)	10 - 50	0,1 mmol/l
base exess (BE)	-25 - 25	0,1 mmol/l
standard base exess (SBE)	-25 - 25	0,1 mmol/l
tatal CO ₂ (TCO ₂)	10 - 50	0,1 mmol/l
buffer base (BB)	0 - 100	0,1 mmol/l
O ₂ saturation of hemoglobin (O ₂ sat)	20 - 100	0,1 %
O ₂ content or concentration (O ₂ CT)	0 - 40	0,1 %
partial O ₂ -press. at 50% O ₂ -sat (P50)	10 - 50	0,01 mmHg
alveolar to arterial oxygen-tension grade (AaDO ₂)	0 - 800	0,1 mmHg
anion gap (A-GAP)	0 - 99	0,1 mmol/l
SHUNT	0 - 50	0,1 %
acid base status	relevant diagnosis recorded on printer	
hematocrite (Hct)	0 - 100 %	0,1 %
data output		
display	illuminated, 15-lines LCD display	
printer	fast, low-noise thermoprinter	
interface	RS 232 and SD Card	
calibration		
automatic calibration		
economy mode		
specimen		
specimen container	capillary, syringe and others	
specimen material	whole blood, serum, plasma/respiratory gas	
electrical data		
voltage	115 V resp. 230 V	
frequency	50/60 Hz	
ambient temperature	12° - 32° C	
dimensions/weight		
height	402 mm	
width	325 mm	
depth	432 mm	
weight	appr. 13 kg	



Attention!

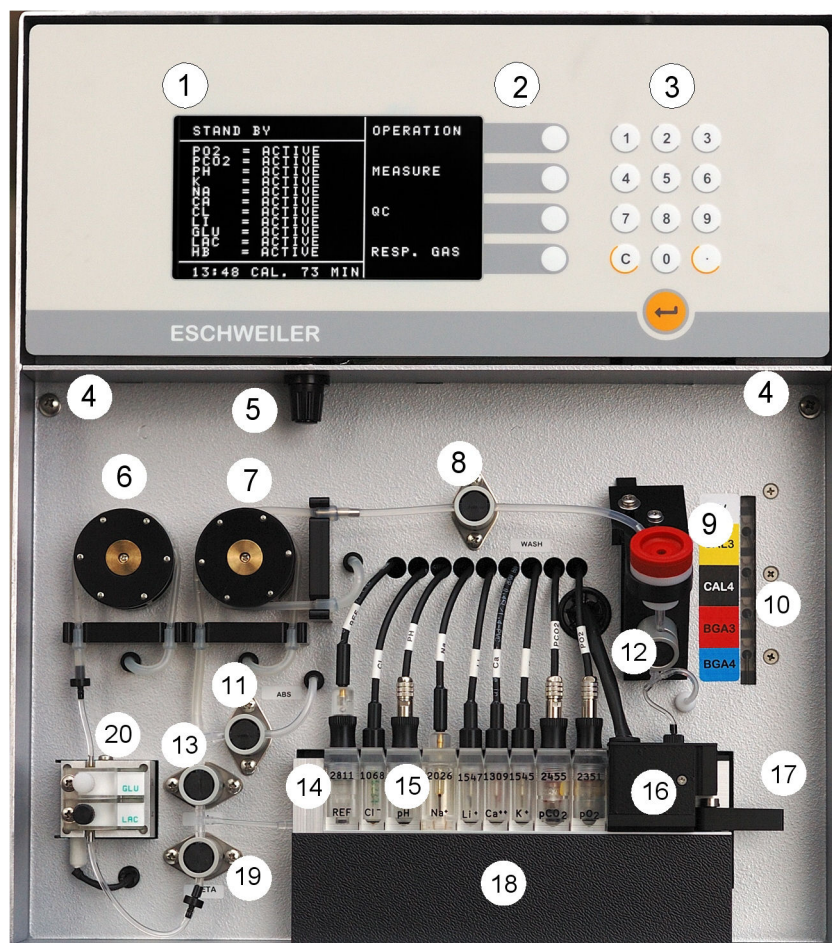
Software functions marked with *
are not accessible during Warming Up!

Software functions marked with **
are not available in BGA types!

Software functions marked with ***
are not available in ISE types!

System Description

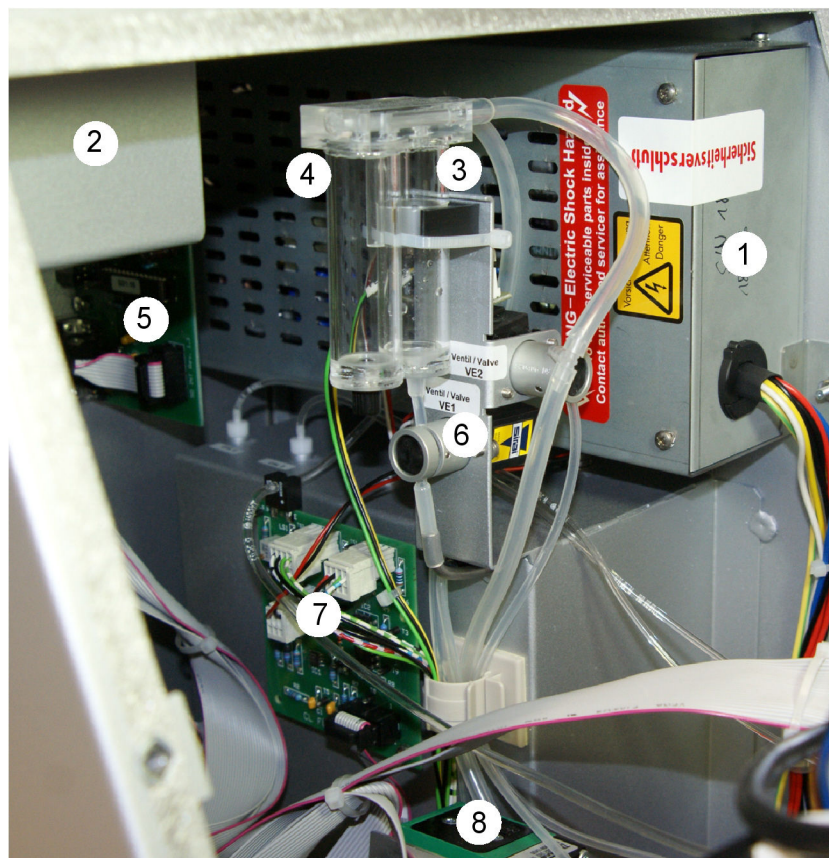
Opened front cover



	Order no.		Order no.
1 - LCD-Display	F100.4.2	11 - Suction-Valve	F200.25
2 - Function keys	50 8 20 70 (keyboard compl.)	12 - Sampleport-Valve	F200.28
3 - Numerical keys	50 8 20 70 (keyboard compl.)	13 - Input-Valve	F200.25
4 - Screw joint of Reagentwall		14 - Sample Light-Barrier	40 7 10 20
5 - Display-Contrast		15 - Thermostat with Sensors	
6 - Peristaltic Pump meta	50 7 40 00	16 - Hb-Sensor type II	50 2 10 01
7 - Peristaltic Pump	50 7 40 00	17 - Sensorcatch	50 7 20 10
8 - WASH-Valve	F200.25	18 - Panel for therm. illumination	50 7 20 21
9 - Sampleport-Insert	1-8.106	19 - Metabolite valve	F200.25
10 - Liquid-Valves for Cal.Solutions	50 8 30 20	20 - Metabolite unit	

System Description

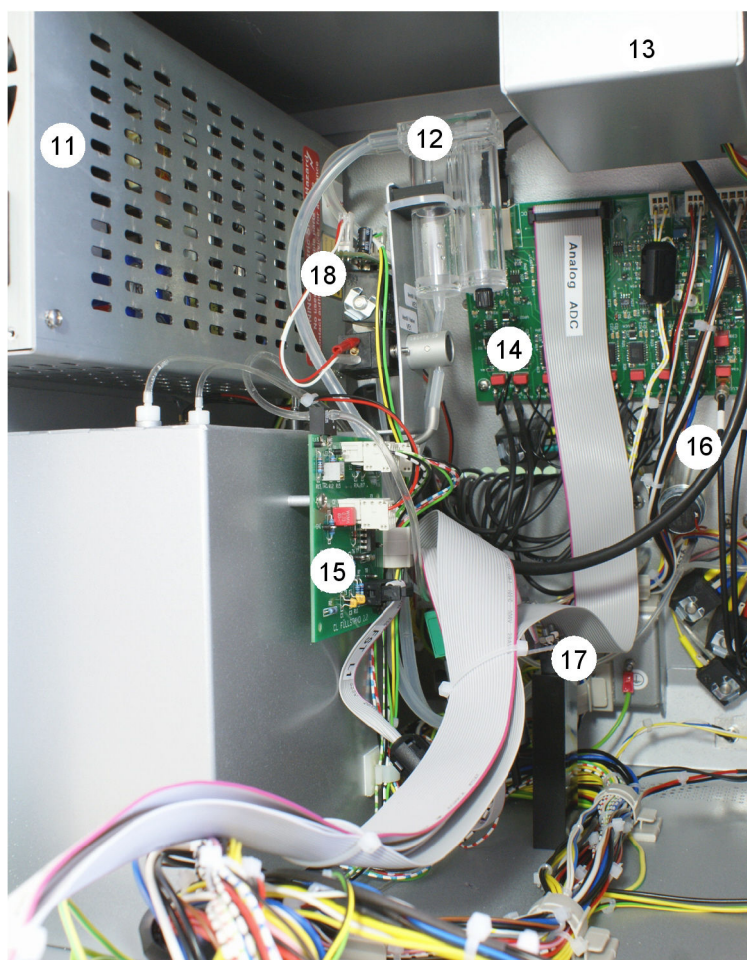
Opened Front



	Order no.
1 - Switching power supply	60 8 10 90
2 - Thermoprinter GPT-4352-60	60 8 20 90
3 - Intermediate Vessel for suction	40 7 10 50
4 - Dampness Absorber	40 7 10 50
5 - Interface RS232 with SD-Card Reader	60 8 20 40
6 - Pinch Valve VE1 and VE2	F200.25
7 - Filling Level Control board CL-FÜLLSTAND	40 8 20 00
8 - Suction Pump	F10.19

System Description

Opened Rear Wall

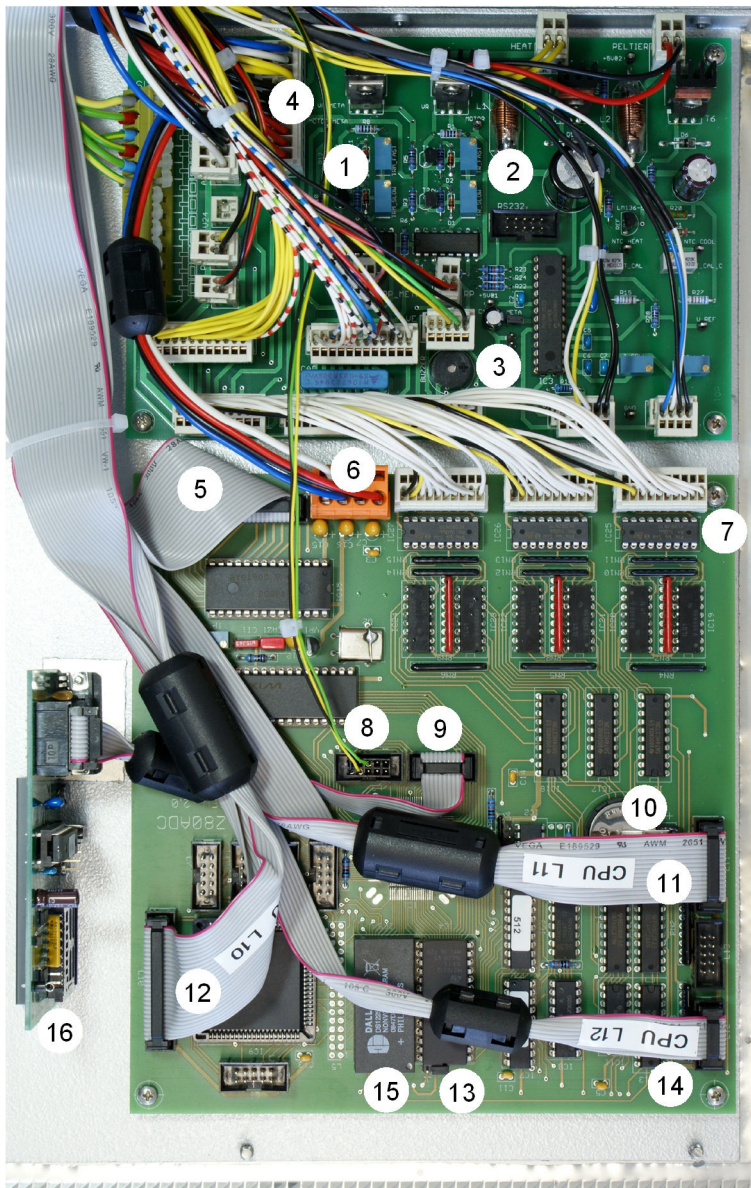


	Order no.
11 - Switching Power Supply	60 8 10 90
12 - Intermediate Vessel	40 7 10 50
13 - Thermoprinter GPT-4352-60	60 8 20 90
14 - Analogboard ESW-ANALOG	60 8 10 xx / 60 8 11 xx
15 - Filling Level Control board CL-FÜLLSTAND	40 8 20 00
16 - Rollerpump Motor with gear	50 7 40 10
17 - Suction Pump	F10.19

System Description

Opened Rearwall, inside

CPU Board Z80ADC 1.2 and Power Supply ESW_MVTC

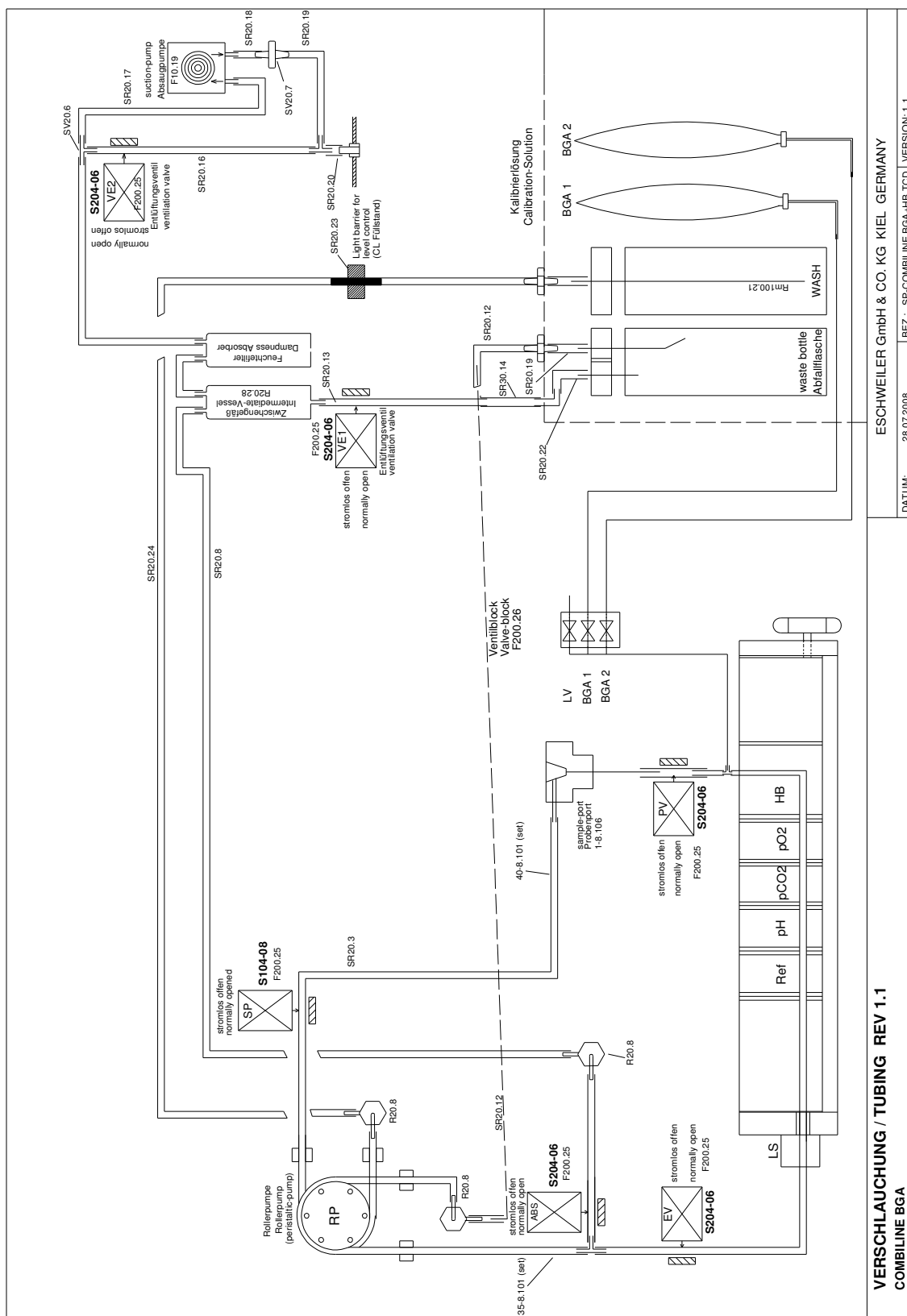


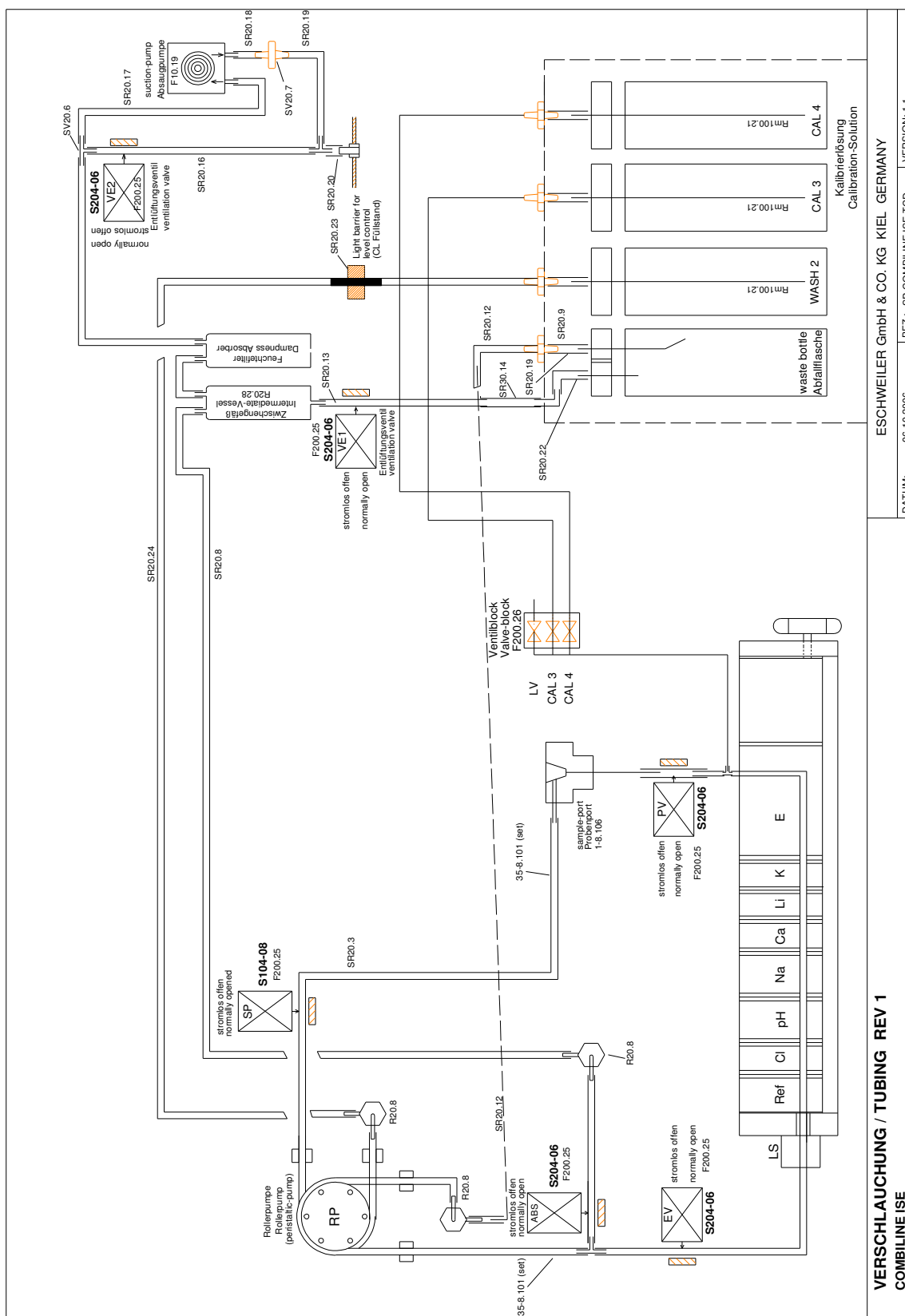
ESW_MVTC 2.0 60 8 10 80

- 1 - Potentiometer Rollerpump 2
- 2 - Potentiometer Rollerpump 1
- 3 - Buzzer
- 4 - Voltage input from Switching Power Supply

CPU CL Z80ADC 1.2 60 8 10 70

- 5 - L4 Connector for Analogboard ESW ANALOG
- 6 - Connector for DC-Supply (+5V)
- 7 - Driver ICs for Valve and Motor Control
- 8 - Printer Interface 9600 Baud
- 9 - Connector for RS232 Interface, 9600 Baud
- 10- Lithium Battery 3V Type BR2325
- 11- L11 LCD-Display
- 12- L10 Keyboard
- 13- Eprom with Analyser Software
- 14- L12 Filling Level board CL FÜLLSTAND
- 15 -RAM
- 16 - SD-Card Reader with RS232 Interface

combi*line* BGA

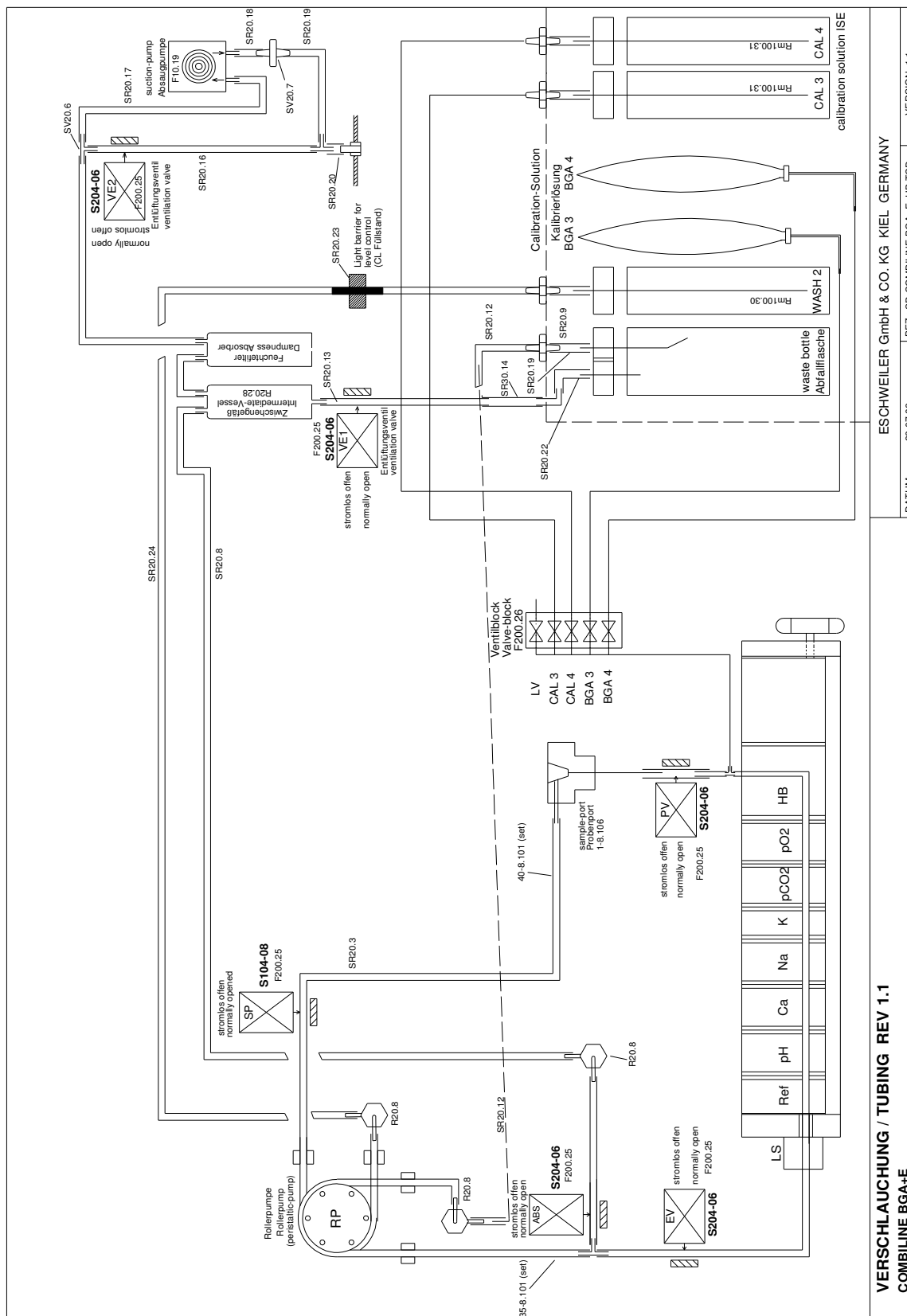


VERSCHLAUCHUNG / TUBING REV 1
COMBILINE ISE

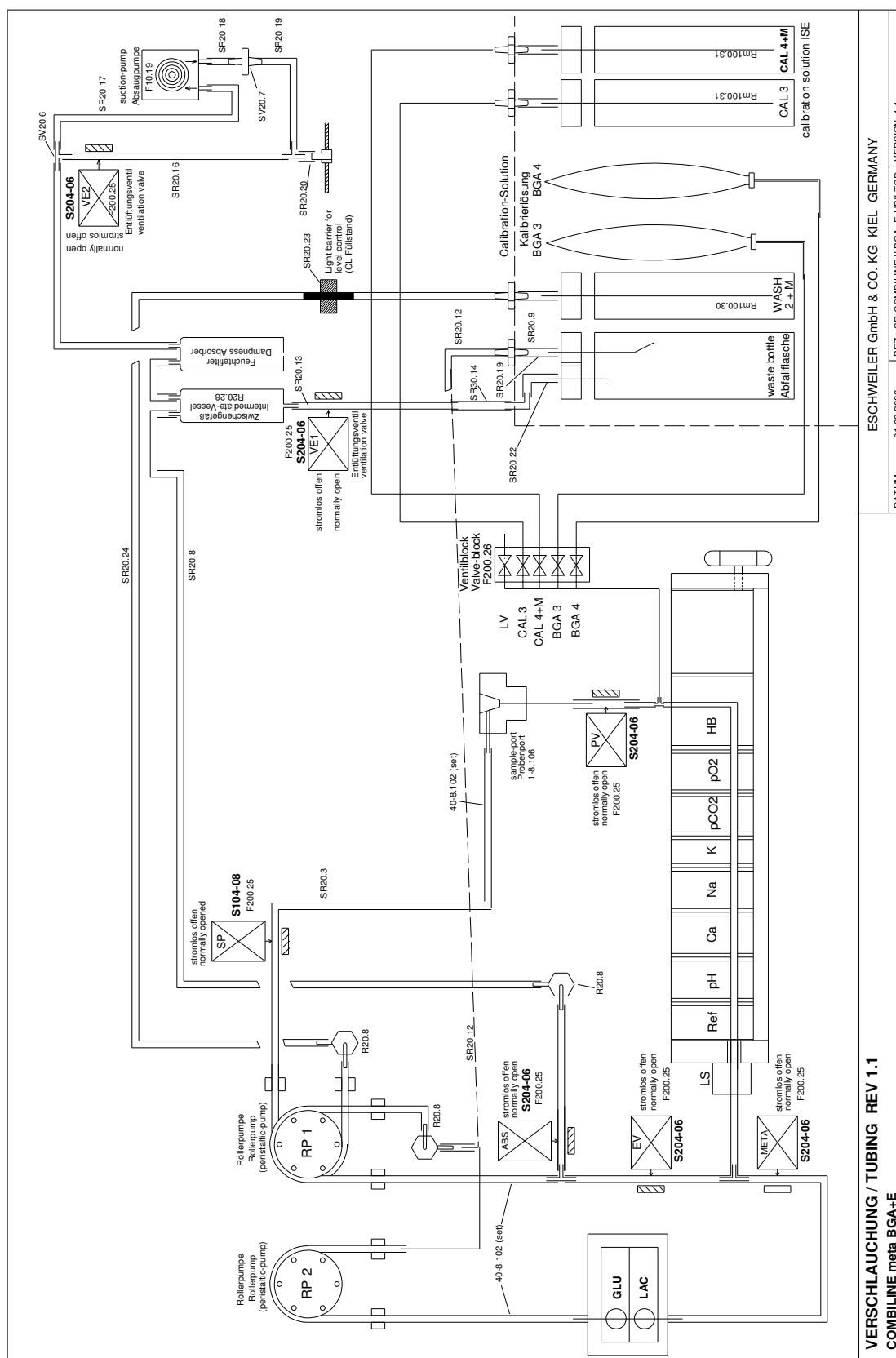
ESCHWEILER GmbH & CO. KG KIEL GERMANY

DATUM: 06.10.2006 BEZ.: SP-COMBILINE ISE TOD VERSION: 1.1

combiLine BGA+E



combi*line* meta



Determination of Valves

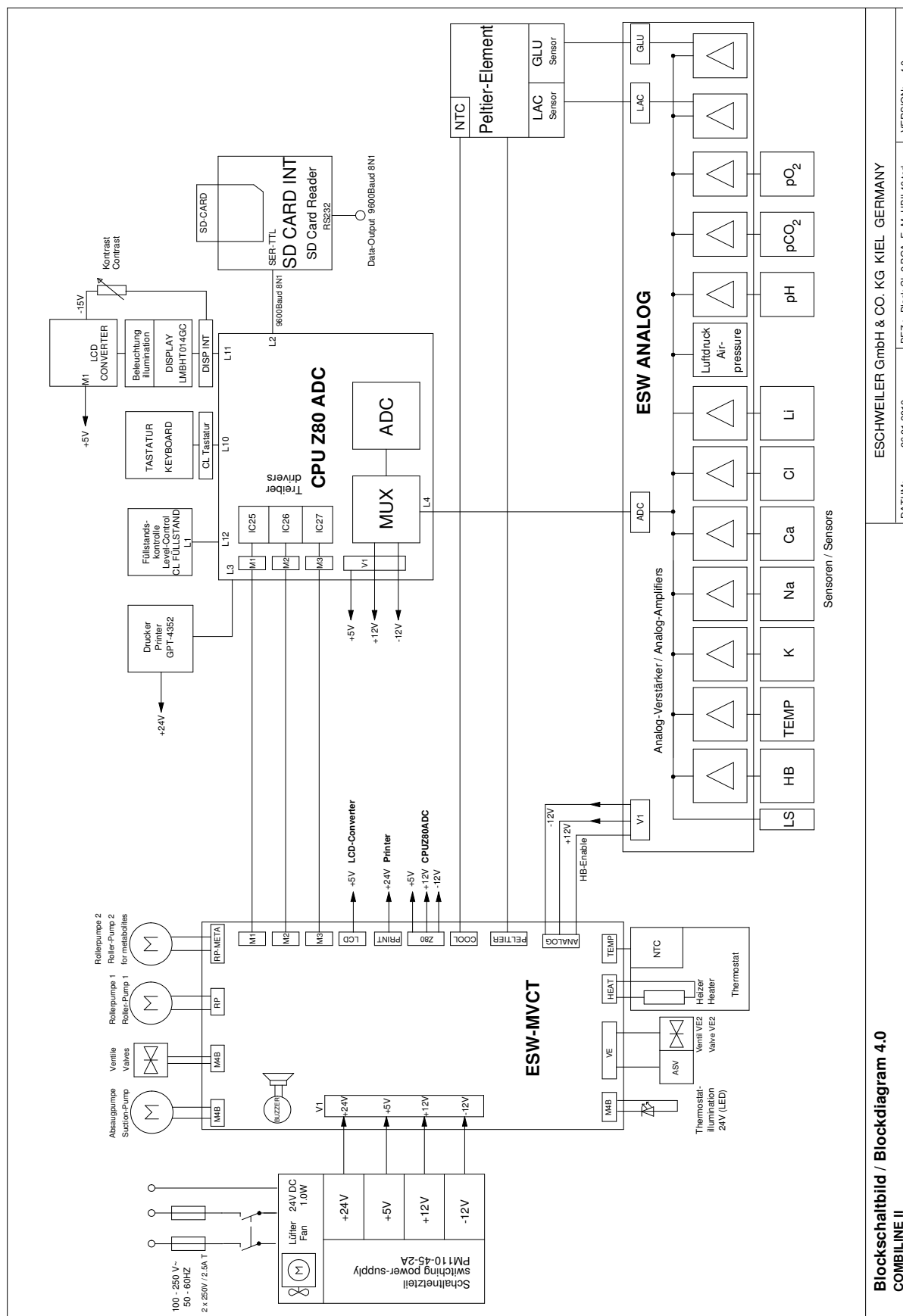
EV	Input-valve, module holder (one stage pinch valve, normally open)
BGA1	Liquid-valve for calibration solution BGA 1 (normally closed) ¹
BGA2	Liquid-valve for calibration solution BGA 2 (normally closed) ¹
BGA 3	Liquid-valve for calibration solution BGA 3 (normally closed) ²
BGA 4	Liquid-valve for calibration solution BGA 4 (normally closed) ²
CAL 3	Liquid-valve for calibration solution CAL 3 (normally closed) ²
CAL 4	Liquid-valve for calibration solution CAL 4 (normally closed) ²
LV	Liquid-valve for ventilation (normally closed)
ABS	Suction-valve (one stage pinch valve, normally open)
META	Valve for triggering of the metabolite sensors ³
VE1	Ventilation-valve, intermediate vessel (one stage pinch valve, norm. open)
VE2	Ventilation-valve, suction pump (one stage pinch valve, normally open)
PV	Sample port valve (one stage pinch valve, normally open)
SP	Rinsing solution valve (one stage pinch valve, normally closed)

¹ not available in combiline with electrolytes or metabolites

² not available in combiline BGA

³ available in combiline meta only

Blockdiagram



Blockschaltbild / Blockdiagram 4.0
COMBILINE II

ESCHWEILER GmbH & CO. KG KIEL GERMANY

VERSION: 4.0

DATUM: 28.01.2010

BEZ.: Block CL 2 BGA-E-M-HBII-40.tcd

Switching Power-Supply

Type: PM110-45-2A

+5V	Supply for Logic (with Protection Diode 1N5630A): Z80 ADC, Level Control board CL Füllstand, LCD Converter
±12V	Analogboard ESW- ANALOG, CL Z80 ADC Multiplexer
+24V	Printer, Valves, Suction-Pump, Thermostat-Heating

Power Supply für Pumps, Valves and Heating

Type: ESW-MVTC

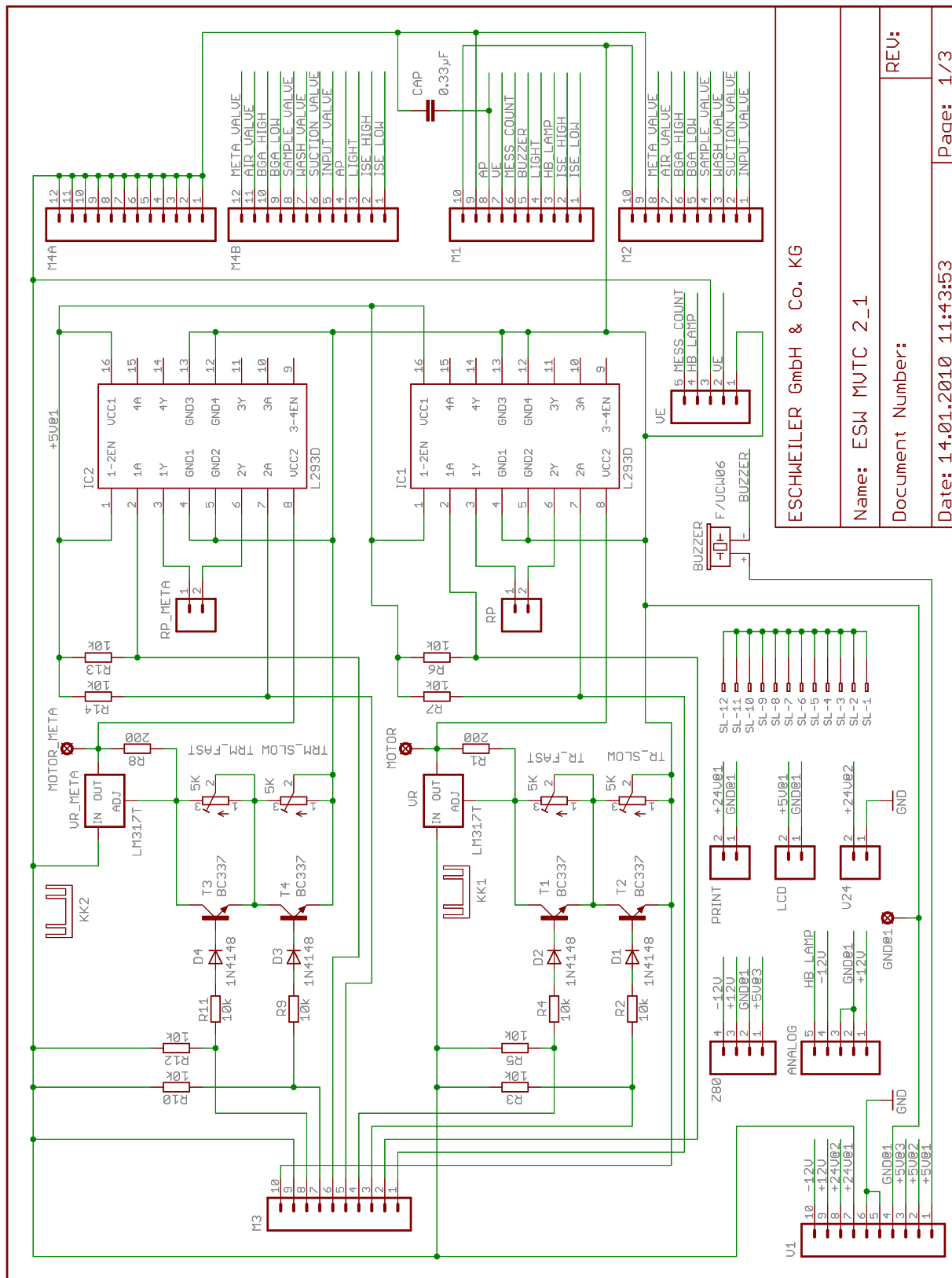
Rollerpump 1

+6,2V	(E slow) Rollerpump 1 - slow speed (Testpoint MOTOR)
+11,5V	(E fast) Rollerpump 1 - fast speed (Testpoint MOTOR)

Rollerpump 2 (available in meta version only)

+6,0V	(E slow) Rollerpump 2 - slow speed (Testpoint MOTOR_META)
+8,0V	(E fast) Rollerpump 2 - fast speed (Testpoint MOTOR_META)

Voltage Supply for Pumps and Valves



ESCHWEILER GmbH & Co. KG

Name: ESW MVTC 2_1

Document Number:

REV:

Date: 14.01.2010 11:43:53

Page: 1/3

Adjustment of the operating voltage for Roller pump RP

Preparations:

1. Switch off the analyser.
2. Open the rear wall.
3. Have a voltmeter ready
4. The board ESW-MVTC is located at the inner side of the rear wall

Adjustment of the roller pump 1:

1. Switch the equipment on again.
2. Press Program key and Select menu SERVICE-TEST.
3. Activate the program 9 REAGENT TEST.
4. Connect the voltmeter to the test-points MOTOR (+) and GND1 (ground).
5. Press key „3“ (calibration solution) to run the roller pump 1 with slow speed.
6. Set the voltage at test-point MOTOR to 6.2V using potentiometer TR_SLOW.
7. Press key „2“ (WASH solution) to run the roller pump 1 with high speed.
8. Set the voltage at test-point MOTOR to 11.5V using potentiometer TR_FAST.

Continue with point 14 if second roller-pump is not available.

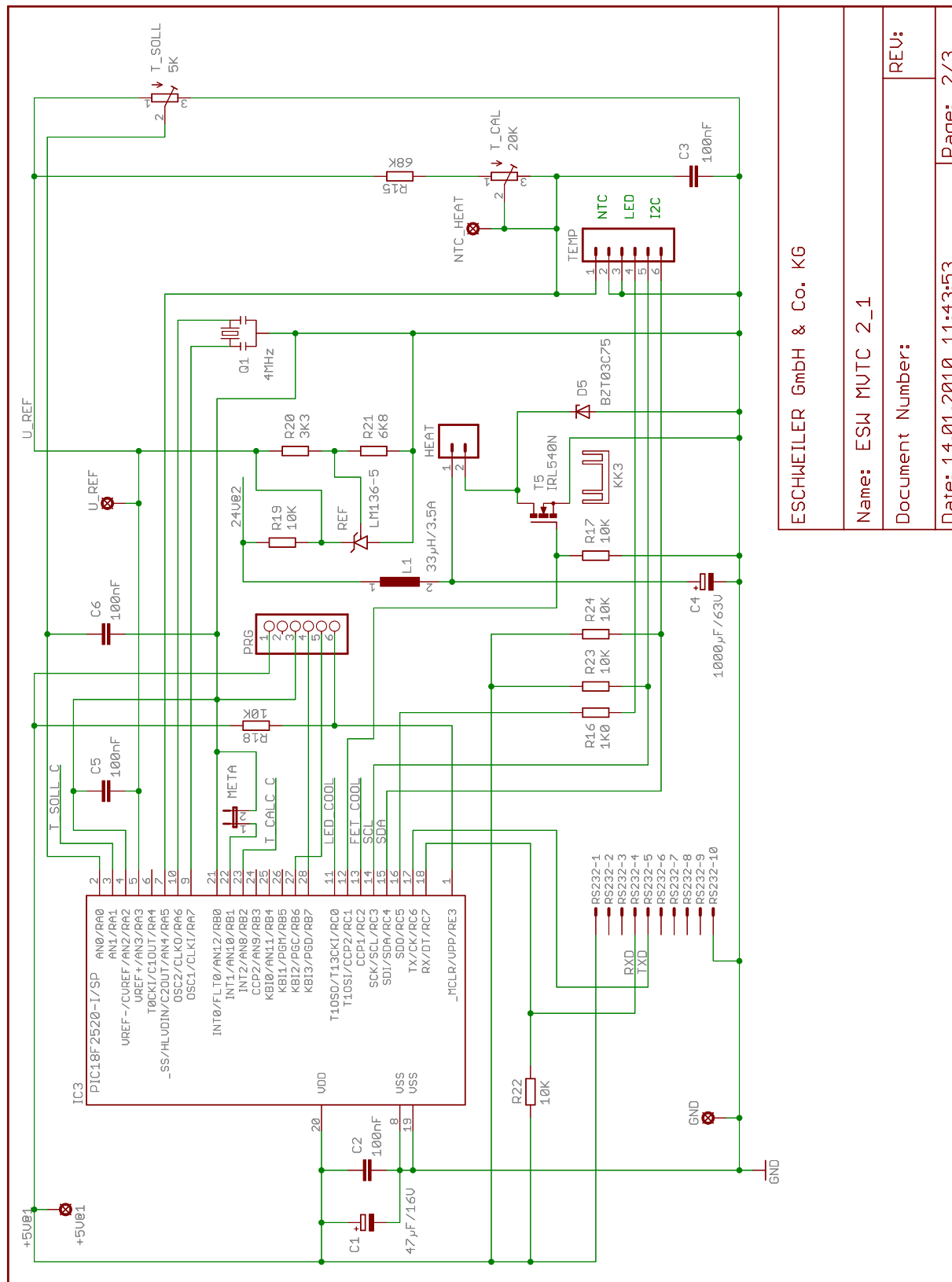
Adjustment of the roller pump 2:

9. Connect the voltmeter to the test-points MOTOR_META (+) and GND1 (ground).
10. Press key „8“ (Meta) to run the roller pump 2 with slow speed.
11. Set the voltage at test-point MOTOR_META to 6.2V \pm 0.3V using potentiometer TRM_SLOW.
12. Press key „7“ (Gas) to run the roller pump 2 with high speed.
13. Set the voltage at test-point MOTOR_META to 8.0V \pm 0.3V using potentiometer TRM_FAST.
14. Switch off the instrument, disconnect Voltmeter
15. Close the rear wall
16. Switch analyser on again

Remark:

The operating voltage for the roller pump has to be checked and adjusted only when an intact, good-as-new roller pump tube is used.

Circuit Diagram Temperature-Regulation



ESCHWEILER GmbH & Co. KG

Name: ESW MVTC 2_1

Document Number:

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Date: 14.01.2010 11:43:53

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Temperature-Regulation

Description:

The Thermostate-Temperature Regulation is located on the power supply board ESW-MVTC

Via the plug connection V1 the low voltage 24 V~/4.5A is supplied. Furthermore the external elements for heavy-duty heating resistors as well as the temperature sensor (both in thermostats) are connected.

Exchange of Temperature regulation board (ESW-MVTC) or the NTC

After exchange of one of these components, the temperature, indicated on the display, is adjusted to 37°C with potentiometer T-CAL. The PIC IC must not be exchanged. Otherwise a re-adjustment of the circuit is required. For this adjustment special equipment is required.

Thermostat temperature correction on-site:

There should be made no adjustments without the required auxiliaries. Adjustments should not be done without contacting Eschweiler Service department!

LED for Temperature control indication:

A yellow LED for Temperature indication is located at the analyser's front, below the reagent-wall. This LED is an indicator for temperature regulation status.

The more the actual thermostat temperature reaches to the nominal value (37°C), the longer the LED is "ON".

The LED is permanently "ON" when the temperature is in a range of $\pm 0.5^{\circ}\text{C}$ from 37°C.

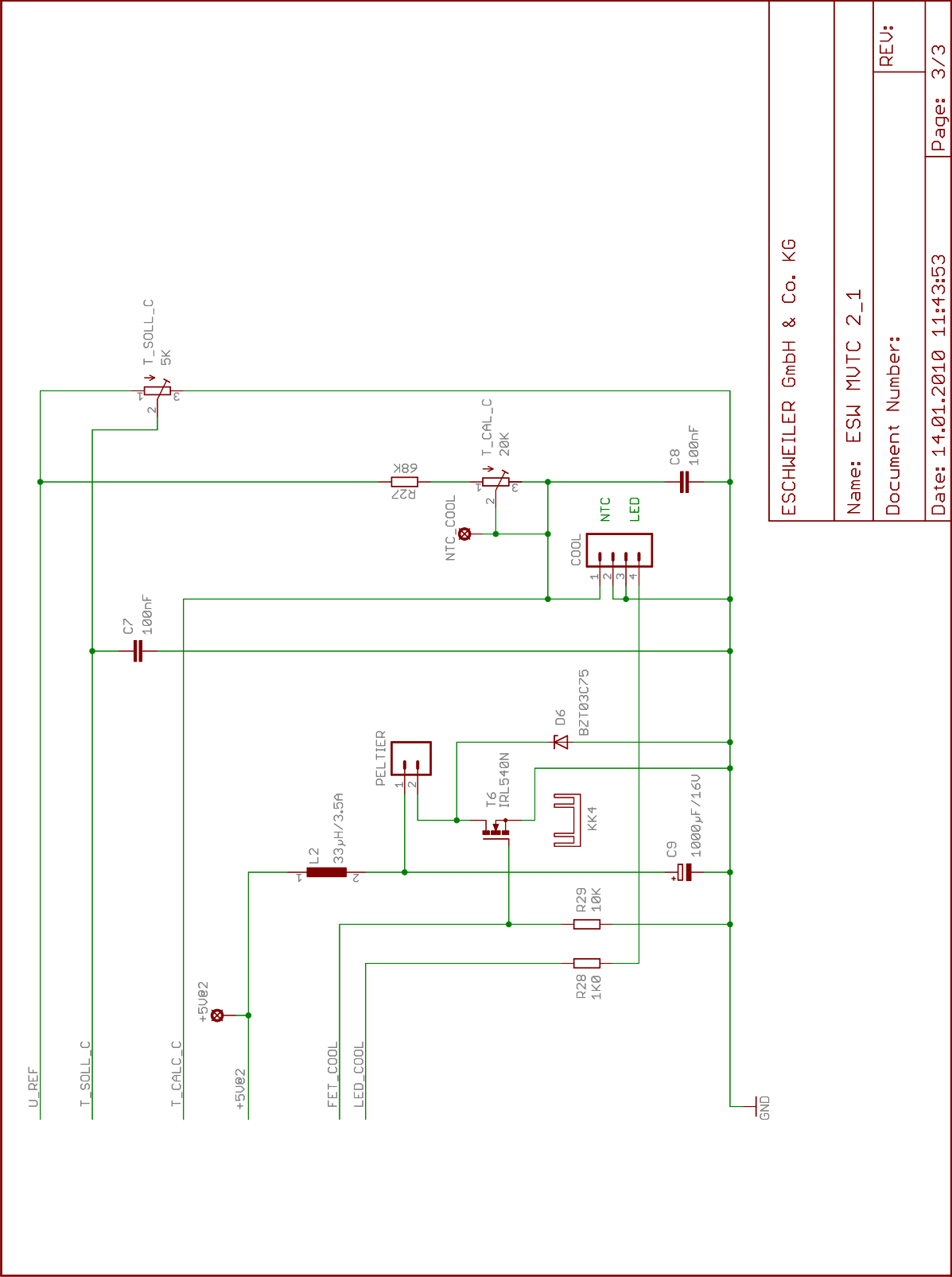
The LED is blinking when the temperature deviation from 37°C is more than $\pm 0.5^{\circ}\text{C}$.

The higher the blinking frequency, the higher is the temperature difference (e.g. Warm-up Phase).

In case of defective NTC-sensor or released temperature safety switch, the LED just blinks very short.

The LED is permanently on when the heating system is functioning.

Metabolite Temperature Regulation, Circuit Diagram



ESCHWEILER GmbH & Co. KG

Name: ESW MUTC 2_1

Document Number:

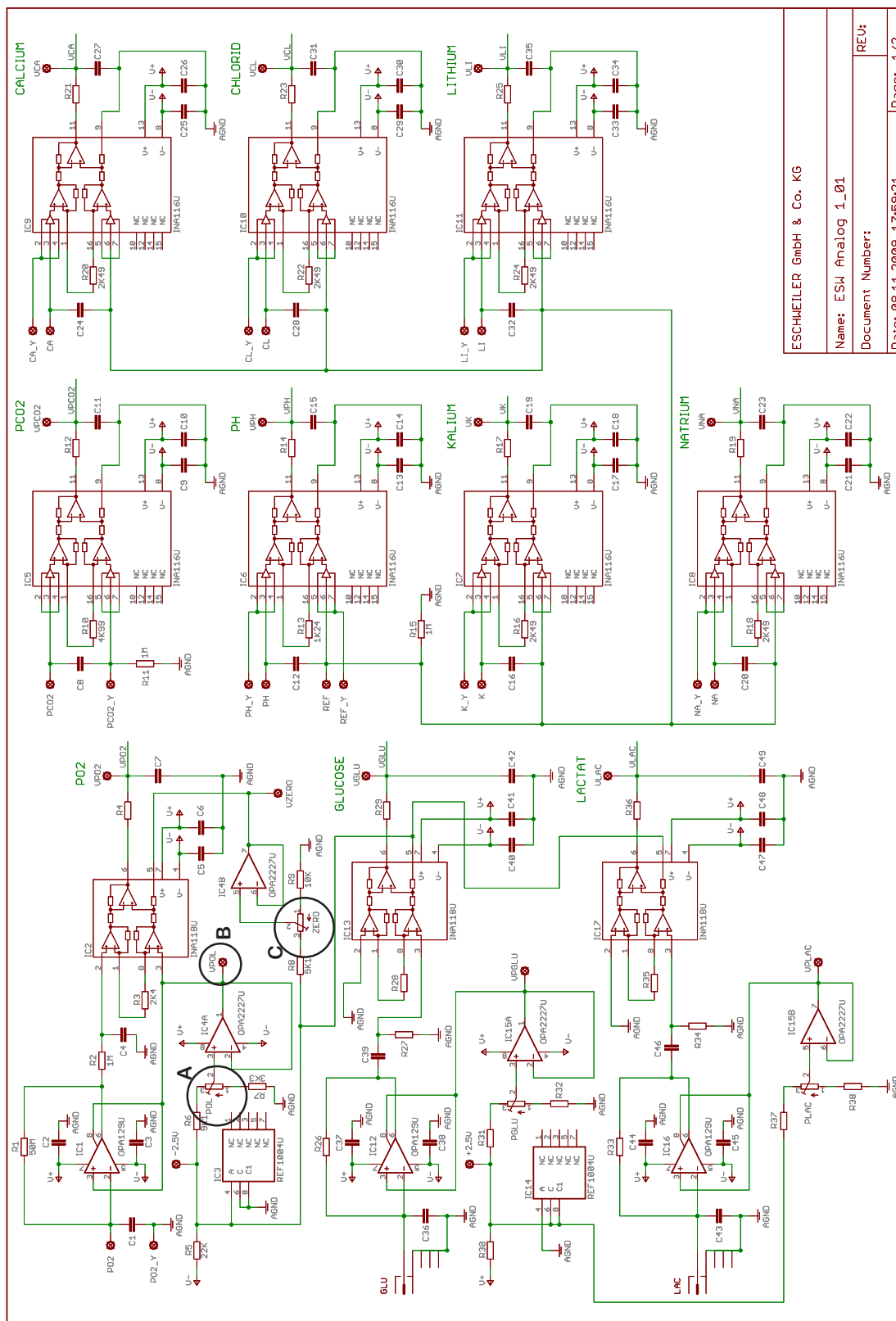
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Date: 14.01.2010 11:43:53

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Analog-Board ESW ANALOG 1_01

Circuit-Diagram for Sensor Amplifiers



ESCHWEILER GmbH & Co. KG

Name: ESW Analog 1_01

Document Number:

Date: 08.11.2009 17:59:21

Page: 1/2

Adjustment of polarization voltage

Preparations:

1. Switch off the equipment
2. Open the rear cover of the instrument
3. The board ESW ANALOG is located at the rear-side of the reagent wall

Adjustment of polarization voltage:

1. Switch the equipment on again
2. Connect a voltmeter to the testpoint UPOL ant pos.B and Ground
3. Adjust the indicated voltage to 0.700V with the potentiometer POL at pos. A
4. Switch the equipment off
5. Close the analogue box, the reagent-wall and the front cover again

Remark:

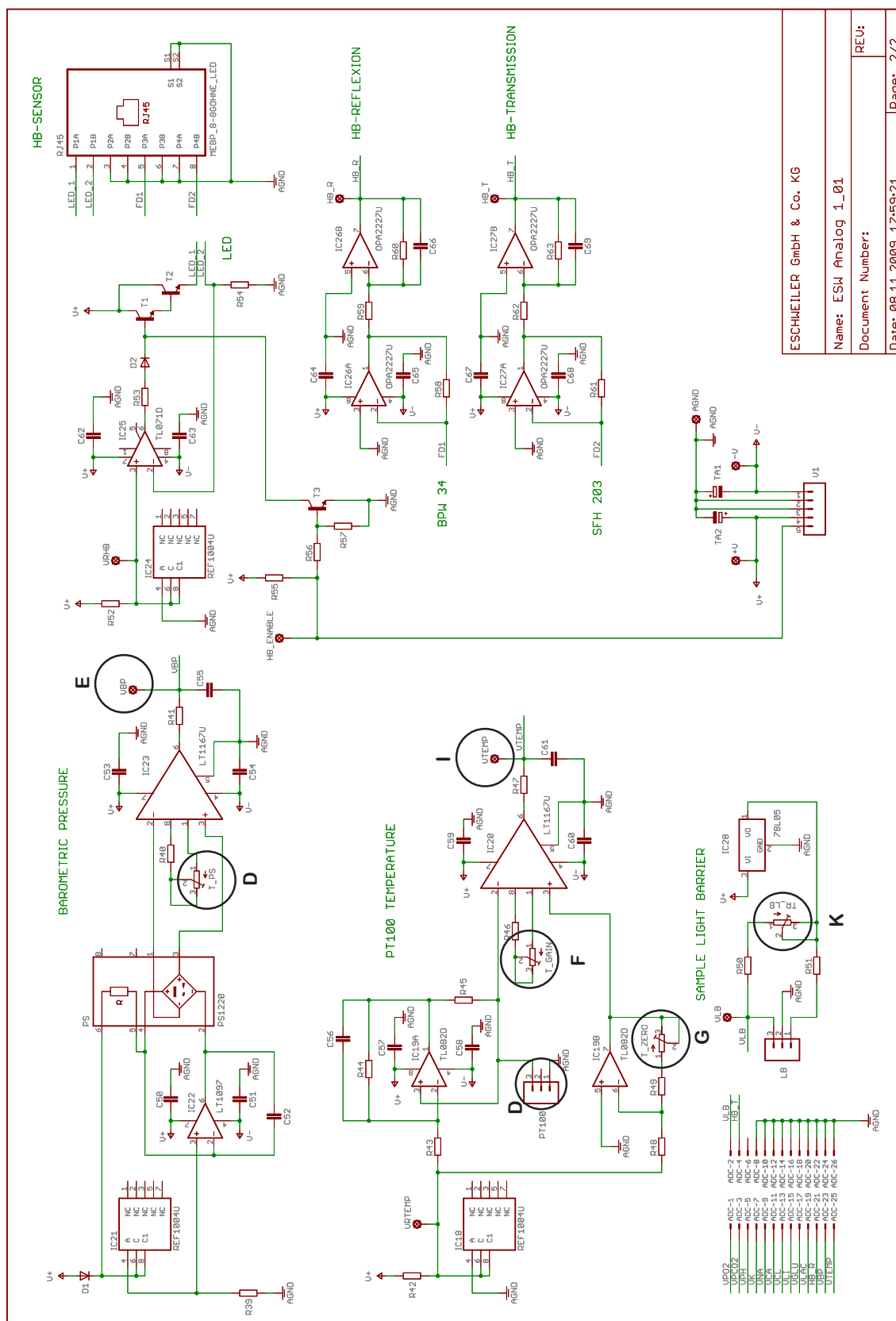
The polarization voltage is connected to the platinum cathode of the pO₂ sensor. It is set to 0.700V at the factory

Adjustment of O₂ zero point

1. Activate Testprogram 5, GAS, in the SERVICE menu and remove the plug from the pO₂-sensor
2. Adjust the voltage, indicated on the screen, to -1.700V with potentiometer ZERO at pos. C
3. Connect sensor cable to pO₂ sensor, stop the Testprogram and start a calibration
4. Repeat this adjustment after approx. 30 min. operation time!

Analog-Board ESW ANALOG 1_01

Circuit-Diagram for BP, TEMP, Sample-Light-Barrier, Hb



Adjustment and Testing of the Barometric Pressure indication

1. Find out the actual atmospheric pressure (Barometric Pressure)
2. Press PROGRAM key and select the menu SERVICE-TEST
3. Select Program 6 AIR / TEMP
4. The atmospheric pressure measured by the internal air-pressure sensor is indicated as follows:
AIRPRESSURE 760 MMHG (example!)
5. Adjust the indicated value to the actual Barometric Pressure with the potentiometer T PS at pos. D

Remark:

A testpoint for measurement of the output voltage of the Barometric Pressure sensor is located at pos. E

Adjustment of thermostate-temperature indication-circuit

Preparation:

1. Switch OFF the analyser
2. Open the front cover of the instrument
3. The board ESW ANALOG is located at the rear side of the reagentwall

The adjustment can be made with a suitable PT100-Transmitter or alternatively with 2 calibrated resistors. The adjustment is made for the value +20°C with a resistance of 107.80 Ohm and for +40°C with a resistance of 115.54 Ohm. At the transmitter and the resistors the same lengths of cable must be used as on the built-in temperature sensor.

Adjustment procedure:

1. Switch the analyser ON again
2. Press PROGRAM key, and Select menu SERVICE-TEST.
3. Then activate the program 6 - AIR / TEMP
4. Disconnect the temperature sensor at plug PT100 at pos. H
5. Set +20°C at the PT100-Transmitter and connect it at pin1 and pin3 of plug M2. Alternatively, connect a precision resistance* of 107.8 Ohm.
6. Set the temperature value in the display to 20.0°C with potentiometer T_ZERO at pos. G
7. Set +40°C at the transmitter or connect a precision resistance* of 115.54 Ohm.
8. Set the temperature value in the display to 40.0°C with Potentiometer T_GAIN at pos F

* Corresponding resistors with suitable plugs are available at ESCHWEILER

It may be necessary to repeat this procedure several times until both values are reached.

Adjustment of the Sample Light-Barrier

The Sample Light Barrier can be adjusted at potentiometer TR_LB at pos. K on the analog board ESW ANALOG

For Adjustment:

1. Open the Reagentwall and move it to the front
2. Press OPERATION key, and select menu SERVICE-TEST
3. Then activate the program 7, LIGHTBARRIER
4. Adjust the voltage, indicated for air, with potentiometer TR_LB at pos. K to a value between 2,000 V - 2.300V
4. Press key TEST (WASH solution is filled into the measuring cell). The indicated voltage must be between 0.300V and 0.500V!

Should it not be possible to reach the a.m. voltage values, an exchange of the Sample Light Barrier or its capillary might be required. For instructions for LB-exchange please note next page.

Sample-Light-Barrier LB

Capillary exchange in Sample Light-Barrier LB

By the time, the sensitivity of the sample-light-barrier can decrease. That means samples as well as calibration solutions are not recognized by the system. This leads to filling level indication for calibration solutions or even to permanent wash-cycles. Samples can be washed out without being measured.

The loss of sensitivity is mainly caused by deposits on the inner surface of the light-barrier-capillary. If an adjustment as described on previous page is not possible, the capillary needs to be replaced. For replacement proceed as follows:

- Activate Reagenttransport Program in menu SERVICE
- Remove sensors on left side (figure 1).
- Remove tube from LB-capillary (a)
- Put the exchange tool on the LB-capillary as shown in figure 2.
- Push the capillary out of the light-barrier as shown in figure 3.
- Take a new LB-capillary, place it on the tip of the exchange tool and push it left into the light-barrier as shown in figure 4.
- Reinstall sensors, connect tube to new LB-capillary and Quit Reagenttransport Program.

After replacement, check and adjust light-barrier voltage as described on previous page.

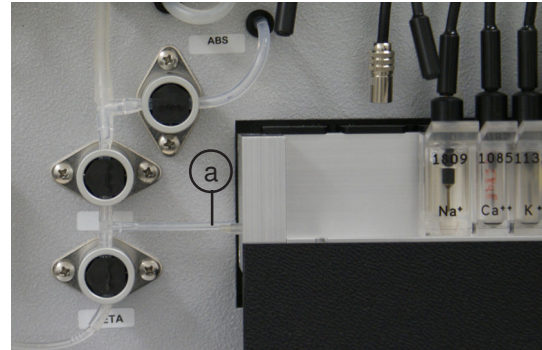


figure 1

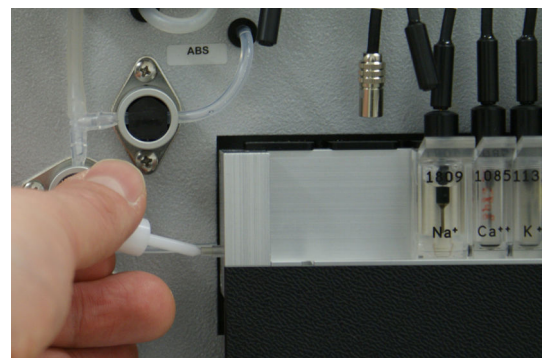


figure 2

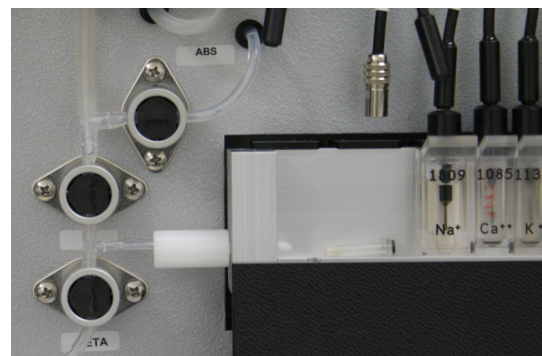


figure 3

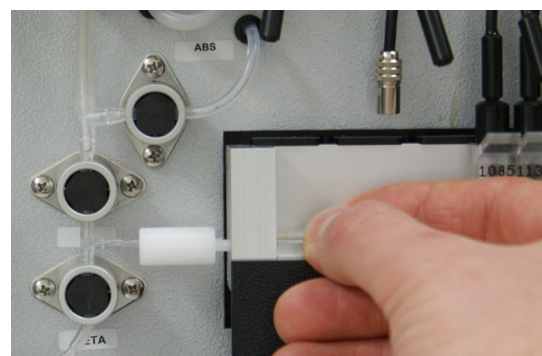


figure 4

Measure method

The Hb-sensor is based on the combination of reflexion (scattered) and Transmission measurement of infrared light.

The data processing of Hb-values in the range of 6 - 30g/dl is done by the Reflexion-measurement method.

The data processing of Hb-values in the range of 3 - 6g/dl is done by the Transmission-measurement method.

The Hb-measure unit is located on the analog amplifier board ESW-ANALOG 1_01.

The following has to be noticed:

- **The use of Hb-calibration is not required**, only the input of two parameters for reflexion and Transmission (HB-R and HB-T) is necessary.
- After setting the Combiline into operation, sensor related parameters have to be entered by keyboard. After that the Hb-sensor is active for measurement. These parameters (HB-R and HB-T) are printed on a white flag at the Hb-sensor cable.
- **The sample volume required for a fully equipped Combiline BGA+E+HB is min. 210 - 240µl. The sample volume required for a combiline BGA+HB is approx. 160µl. So it is of particular relevance to use capillaries with adequate volume.**
- Please note that this measure method is suitable for measurement of whole-blood only! Quality controls are not usable!
- The measure range of the Hb-sensor is 3 - 30g/dl
- Hb will be measured if the sample light-barrier detects a whole-blood sample. Otherwise the programmed standard Hb-value is displayed (e.g. 15g/dl) and used for the calculation of the acid-base parameters.
- In case of too less sample volume, a "Transmission-voltage" of -4.000V is detected. The displayed Hb-value will be 0.0g/dl then. This can be observed on a sensor-parameter printout which can be made after a sample measurement (see attached example of printout)

Activation of Hb-Sensor type II

Carry out of an Hb-Sensor activation in STAND-BY mode

In order to maintain the measuring accuracy for determination of Hb and to activate the Hb-sensor, an input of two factors HB-R and HB-T has to be carried out in STAND-BY mode

In case the COMBILINE was switched off for less than 24 hours the Hb-factors are retained in the memory and the sensor remains ACTIVE.

In case the COMBILINE was switched off for more than 24 hours the Hb-factors have to be entered as described below, the Hb-sensor is marked with OFF.

The mentioned Hb-factors are printed on a white flag at the Hb-sensor cable (see attached photo)

Carry out Hb-factor input to activate the Hb-sensor:

- Press the **5**-key in OPERATION MENU to perform the Hb-activation process, the following dialogue appears:

HB-SENSOR

HB R : 0.000

HB T :

- Enter the **HB-R value** given on the white ensign at the Hb-sensor by keypad e.g. 0.970 and press the Enter-key to confirm.

The following dialogue appears:

HB-SENSOR

HB R : 0.970

HB T : 0.000

- Enter the **HB-T value** given on the white ensign at the Hb-sensor by keypad e.g. 0.517 and press the Enter-key to confirm.
- The input range for HB-R and HB-T is 0.300 to 1.800

For quality control of the Hb-Sensor, whole blood specimens whose Hb-concentration have already been determined with the help of suitable measuring methods might be used (e.g. oximeter).

HB - SENSOR		
HBR / HBT	0.970	0.517
MESS. [mV]	-1182	-320

printout of Hb-sensor parameter

HB/R = Reflexion factor

HB/T = Transmission factor

MESS = Hb-sensor voltages for Reflexion and Transmission measurement of the last sample measurement (in millivolt)

Hb-factors HB-R and HB-T

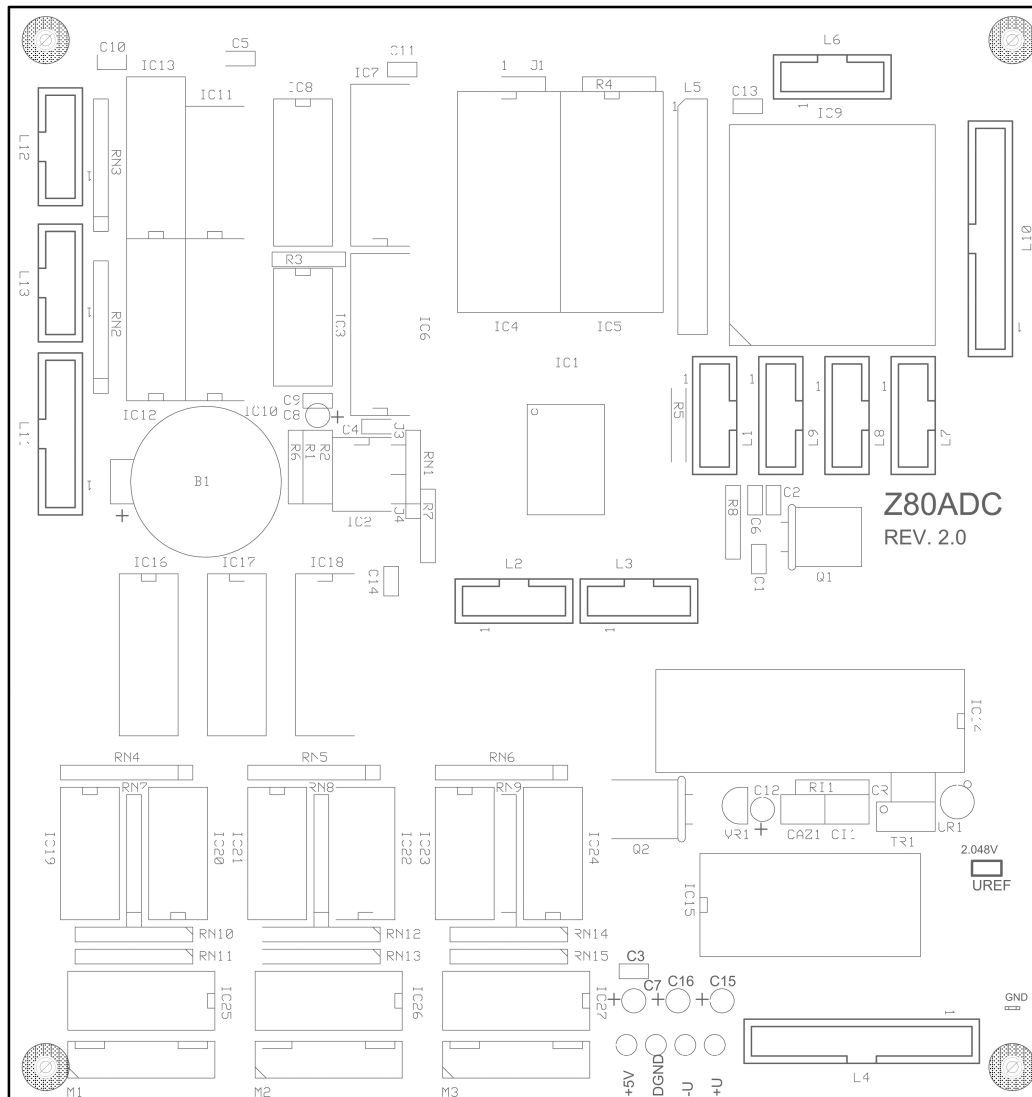
Hb-sensor type II



Hb-sensor type II installed in combiline (optional)

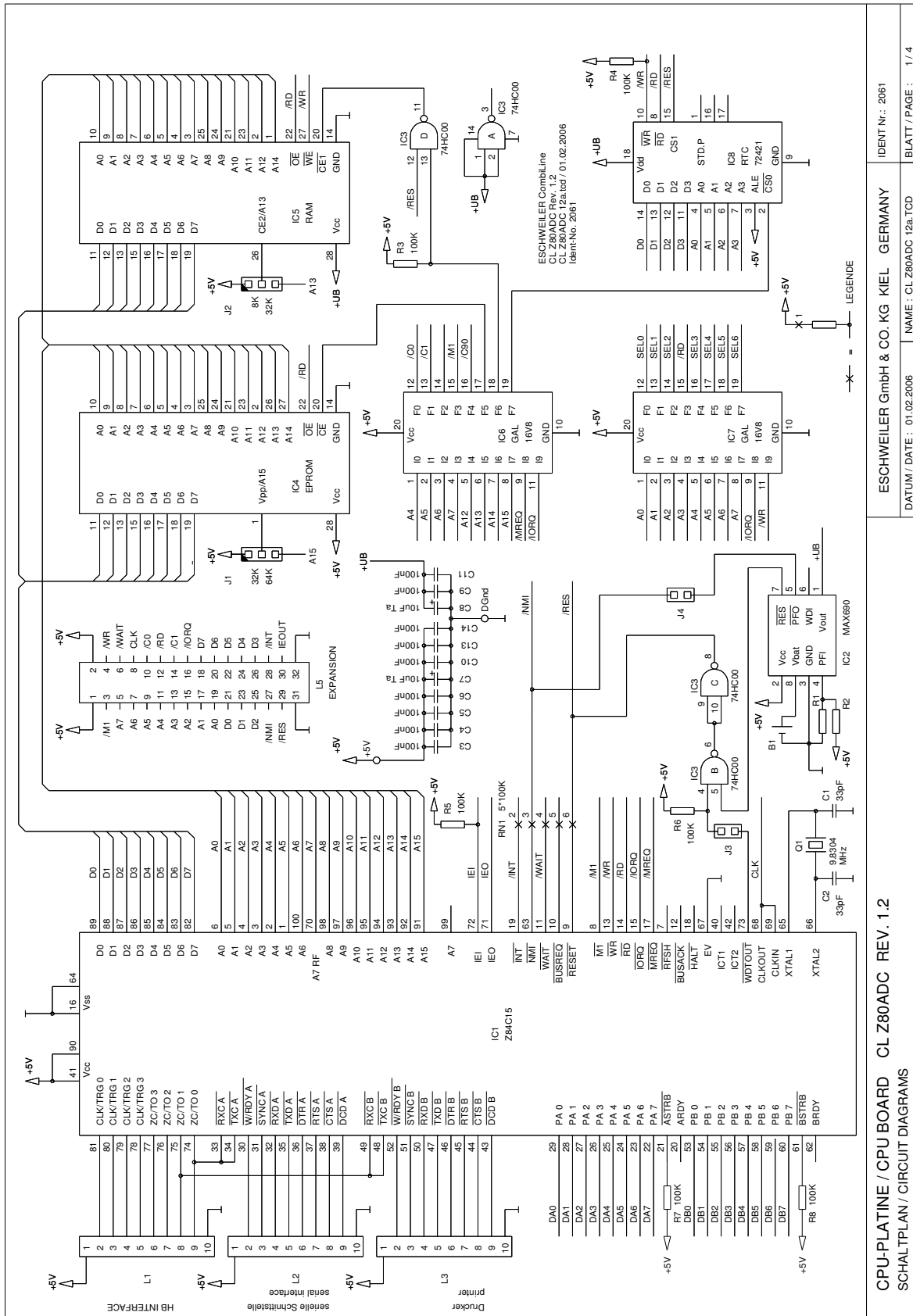
CPU Board CL Z80 ADC12

Layout



CPU Board CL Z80 ADC12

Circuitdiagram 1/3



CPU-PLATINE / CPU BOARD CL Z80ADC REV. 1.2

SCHALTPLAN / CIRCUIT DIAGRAMS

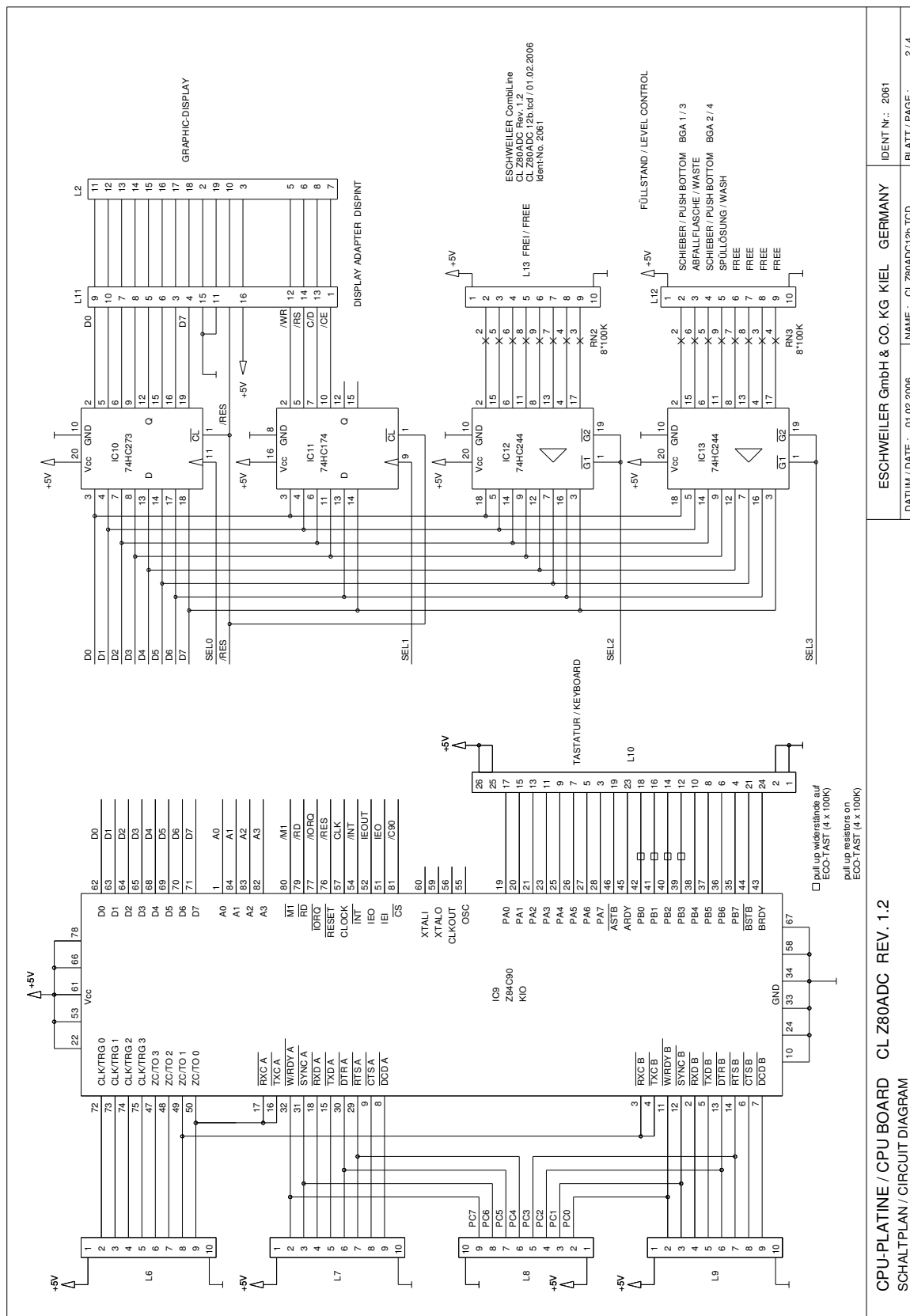
ESCHWEILER GmbH & Co. KG KIEL GERMANY

DATUM / DATE : 01.02.2006 NAME : CL Z80ADC 12a.TCD IDENT.Nr.: 2061

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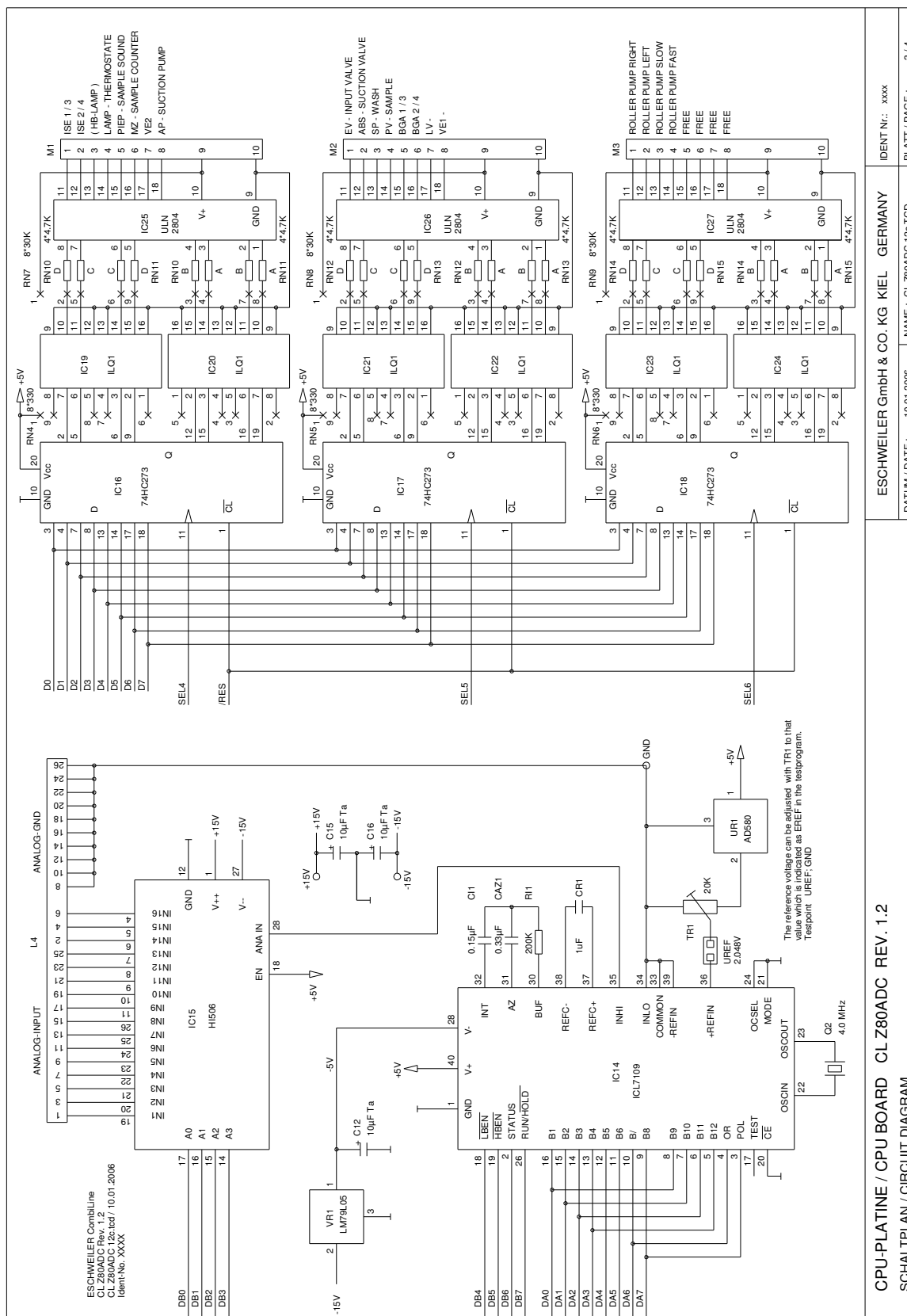
CPU Board CL Z80 ADC12

Circuitdiagram 2/3



CPU Board CL Z80 ADC12

Circuitdiagram 3/3



CPU-PLATINE / CPU BOARD CL Z80ADC REV. 1.2
SCHALTPLAN / CIRCUIT DIAGRAM

ESCHWEILER GmbH & Co. KG KIEL GERMANY
IDENT Nr.: xxxx
DATUM / DATE: 10.01.2006
NAME: CL Z80ADC 12c.TCD
BLATT / PAGE: 3 / 4

Specification

AD-conversion:	(2 x 8 Bit parallel) 12 Bit AD-converter, ICL7109 int., range -4.096V to +4.096V, resolution 1mV. 16 channel multiplexer, HI506
Driver Output	(24 pieces) 3 x 8 Bit outputs, with D-Latch (74HC273), Optocoupler (galvanic insulation) and driver circuits for loads up to 1A (ULN2803)
Display:	Graphic-display NLC240x128BTGLE at L11 via ECODISP
Level control:	(1 x 8 Bit) 8 Input-Ports for checking the filling levels of reagents via L12 CL FÜLLSTAND
Serial interface:	1. External interface RS-232 SD INT at L2 2. Thermo printer at L3
EPROM:	64KB Program (27C512)
RAM:	8KB (8K x 8)
Keyboard:	Two parallel Ports at L10
Reset-component:	battery operation, automatic reset generation, switch over to battery operation
4 Timer and counter channels:	Baudrate generation (2 channels) Timer (multitasking software modul)

Remark:

An automatic reset is generated if the operation voltage of the CPU board becomes lower than 4.75V or higher than 5.25V.

Serial interface with SD-Card Reader RS-232 SD INT 1.4

Technical Data:

Baudrate: 9600 bit/sec

Databit: 8

Parity: no

Startbit: 1 (STX = 02HEX))

Stopbit: 1 (ETX = 03HEX)

no handshake (unidirectional)

connector: terminal RS232 at the rear panel of the instrument

Description:

All data which is sent to the printer after completion of a sample measurement, will also be transmitted to the RS232 interface at the same time together with CR (carriage return) and LF (line feed) at the end of the line. The transmission is unidirectional, there is no dialog between COMBILINE and PC. The data has to be received in a polling mode after starting a measurement. The data is given out in standard ASCII code.

Data recalled from the memory (SD-Card) will not be sent via RS232 !

The data transmission is unidirectional only.

Remark:

The data given by the interface can be detected by any terminal program for example TERMINAL.

Serial Interface RS-232 SD INT 1.4

Printout:

Example of print out of measuring results with corresponding data output

ESCHWEILER COMBI.LINE			Data output	Meaning
NAME :			(position no.,Value)	(Parameter unit)
			STX	Start of Text (02HEX)
#	0945250808		80,CL3000	Type of analyser
DATE	09:45 25.08.08		81,0945250808	Sample number
			82,09:45,25.08.08	Time and Date
PL	760	mmHg	0,171.1	pO ₂ mmHg or kPa
TEMP	37.0	C	1,1.8	pCO ₂ mmHg or kPa
HB	15.0	g/dl	2,7.373	pH
HCT	45.0	%	3,5.9	K ⁺ mmol/l
FIO2	20.9	%	4,104	Na ⁺ mmol/l
RQ	0.85		5,1.38	Ca ⁺⁺ mmol/l
			6,141	Cl ⁻ (QC) mmol/l
PO2	171.1	mmHg	7,0.92	Li ⁺ mmol/l
PCO2	1.8	mmHg	8,0.0	GLU mmol/l
PH	7.373		9,0.0	LAC mmol/l
H+	42.4	nmol/L	10,15.0	Hb g/dl
K	5.9	mmol/l	11,45.0	HCT %
NA	104	mmol/L	12,42.4	H ⁺ nmol/l
CA	1.38	mmol/L	13,1.36	Ca ⁺⁺ 7.4 mmol/l
CA 7.4	1.36	mmol/L	14,126	Cl ⁻ (Blood / Serum) mmol/l
CL	126	mmol/L	15,37.0	Temperature °C
LI	0.92	mmol/L	16,20.9	FIO ₂ %
			17,0.85	RQ
HCO3A	1.0	mmol/L	18,1.0	HCO3A mmol/l
HCO3S	13.3	mmol/L	19,13.3	HCO3S mmol/l
BE	-19.0	mmol/L	20,-19.0	BE mmol/l
SBE	-21.5	mmol/L	21,-21.5	SBE mmol/l
TCO2	1.1	mmol/L	22,1.1	TCO ₂ mmol/l
BB	29.0	mmol/L	23,29.0	BB mmol/l
O2SAT	99.4	%	24,99.4	O ₂ SAT %
O2-CT	20.5	%	25,20.5	O ₂ -CT %
P50	27.7	mmHg	26,27.67	P50 mmHg
AADO2	-24.2	mmHg	27,-24.20	AADO ₂ mmHg
A GAP	-17.1	mmol/L	28,-17.1	A-GAP mmol/l
SHUNT	4.4	%	29,4.4	SHUNT %
ACID / BASE STATUS			30,171.1	pO ₂ , temp. correct. mmHg
FULLY COMP. RESP.			31,22.81	pO ₂ , temp. correct. kPa
ALKALOSIS AND / OR			32,1.8	pCO ₂ , temp. correct. mmHg
FULLY COMP. NON-RESP.			33,0.25	pCO ₂ , temp. correct. kPa
ACIDOSIS			34,7.373	pH, temp corrected
			35,0.00	GLU mg/dl
			36,0.00	LAC mg/dl
			37,760	Barometric Pressure mmHg
			38,101.3	Barometric Pressure kPa
			65	Sample type (MESART)*
			0	Timeouts (ADCMSK)*
			255	Active Sensors (MESMSK)*
			ETX	End of Text (03HEX)

* see next page for description

Meaning of the last three Values of a data output:

1. Value - MESART= kind of measurement
2. Value - ADCMSK = sensors which exceeded the permissible time for measurement (measure-value with ?)
3. Value - MESMSK = sensors which were ACTIVE during measurement

All values are available in ASCII-Format as hexadecimal value. The value range is from 0 to 32768.

Explanation:

Bit	Valence	MESART	ADCMSK, MESMSK
00	1	Syringe	PO2
01	2	Capillary	PCO2
02	4	BGA only	PH
03	8	ISE only	K
04	16	QC	NA
05	32	Respiratory Gas	CA
06	64	Serum, Plasma	CL
07	128	Blood	LI
08	256	-	HB
09	512	-	-
10	1024	-	-
11	2048	-	-
12	4096	-	-
13	8192	-	-
14	16384	-	-
15	32768	-	-

Example for MESART:

65	64 + 1	Serum, Plasma ; Syringe
82	64 + 16 + 2	Serum, Plasma ; QC ; Capillary
133	128 + 4 + 1	Blood ; BGA only ; Syringe

Example for ADCMSK:

0	0	All Sensors comply with permissible measure times
3	2 + 1	pO ₂ + pCO ₂ did not comply with permissible measure times

Examples for MESMSK:

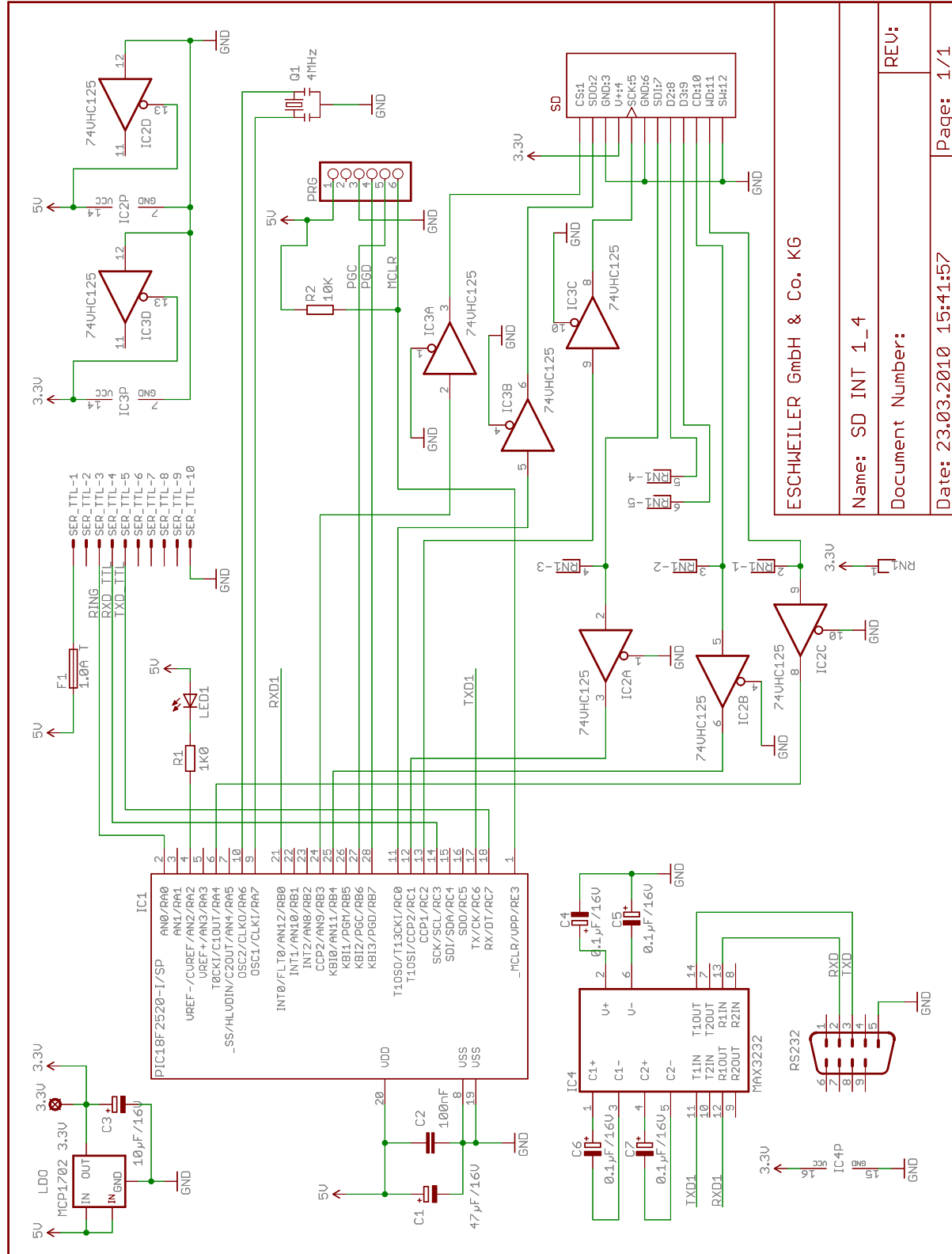
255	128+64+32+16+8+4+2+1	pO ₂ , pCO ₂ , pH, K ⁺ , Na ⁺ , Ca ⁺⁺ , Cl ⁻ , Li ⁺ were ACTIVE during measurement
7	4 + 2 + 1	pO ₂ + pCO ₂ + PH were ACTIVE during measurement

Layout

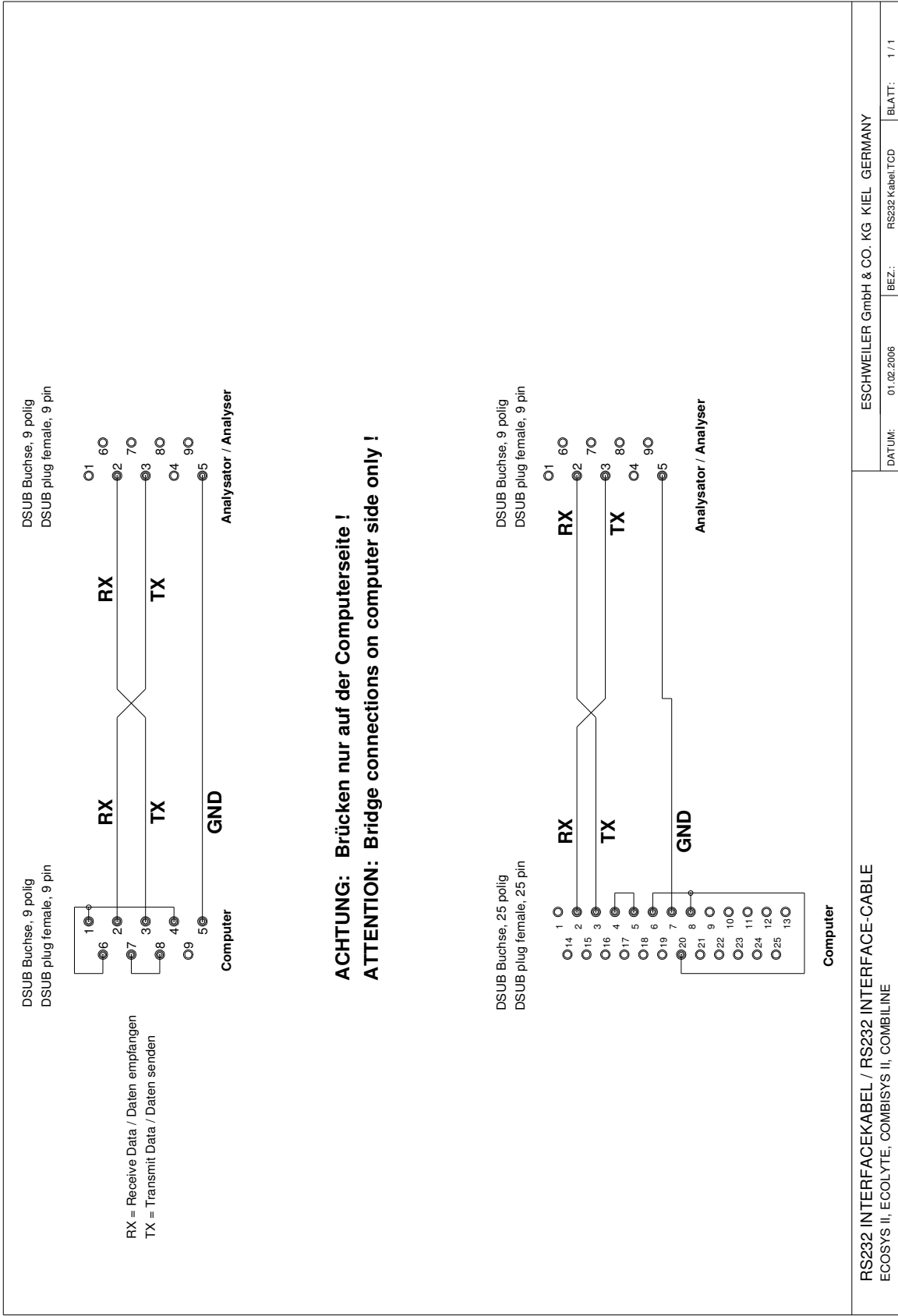


Serial Interface RS-232 SD INT 1.4

Circuit Diagram



Interface Cable



Fill Level Control CL FÜLLSTAND

Description:

Via L2 the waste bottle sensor is connected. The control of the Calibrants is made by the Sample Light Barrier in the Sensorholder (Thermostat).

Via L1 the voltage supply (+5V / GND digital) and the outputs of the comparators are connected. The switch thresholds of the light barrier LS1 for WASH is adjusted with potentiometer TR1.

The light barriers must fulfil the following conditions:

1. Rinsing solution/calibration solution in tube $U_{\max} = 0.300 \text{ V}$
2. Air in tube $U_{\min} = 1.000 \text{ V}$

The outputs of the comparators supply the following signals:

	empty	full
rinsing solution T8	0 V	+5 V
Push bar BGA 1/3 T4	0 V	+5 V (released / pressed)
Push bar BGA 2/4 T3	0 V	+5 V (released / pressed)
waste bottle T5	+5	0 V

Check of the waste bottle control

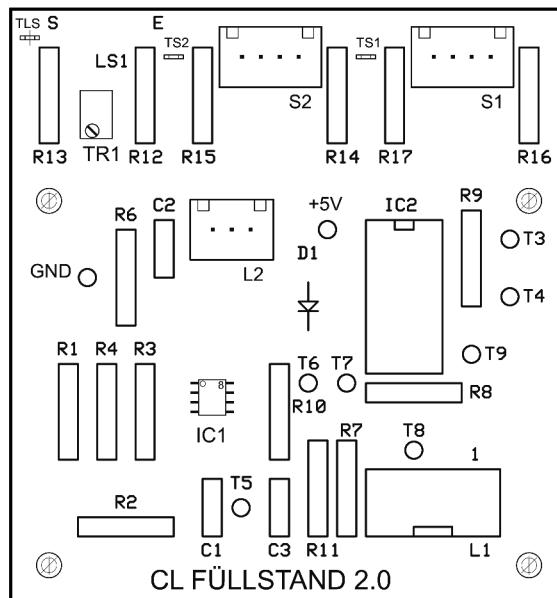
1. Reference voltage at T6 = 2.500 V
2. Sensors of waste bottle:
 - in air, T7 approx. 3.500 V
 - in tap water, T7 approx. 2.000 V
 - in distilled water T7 approx. 2.400 V

For testpoints (T...) see circuit diagram CL FÜLLSTAND

Transport of calibration solutions CAL3, CAL4, BGA1, BGA2, BGA3 and BGA4 is controlled by the Sample Light Barrier during calibration procedure!

Fill Level Control CL FÜLLSTAND

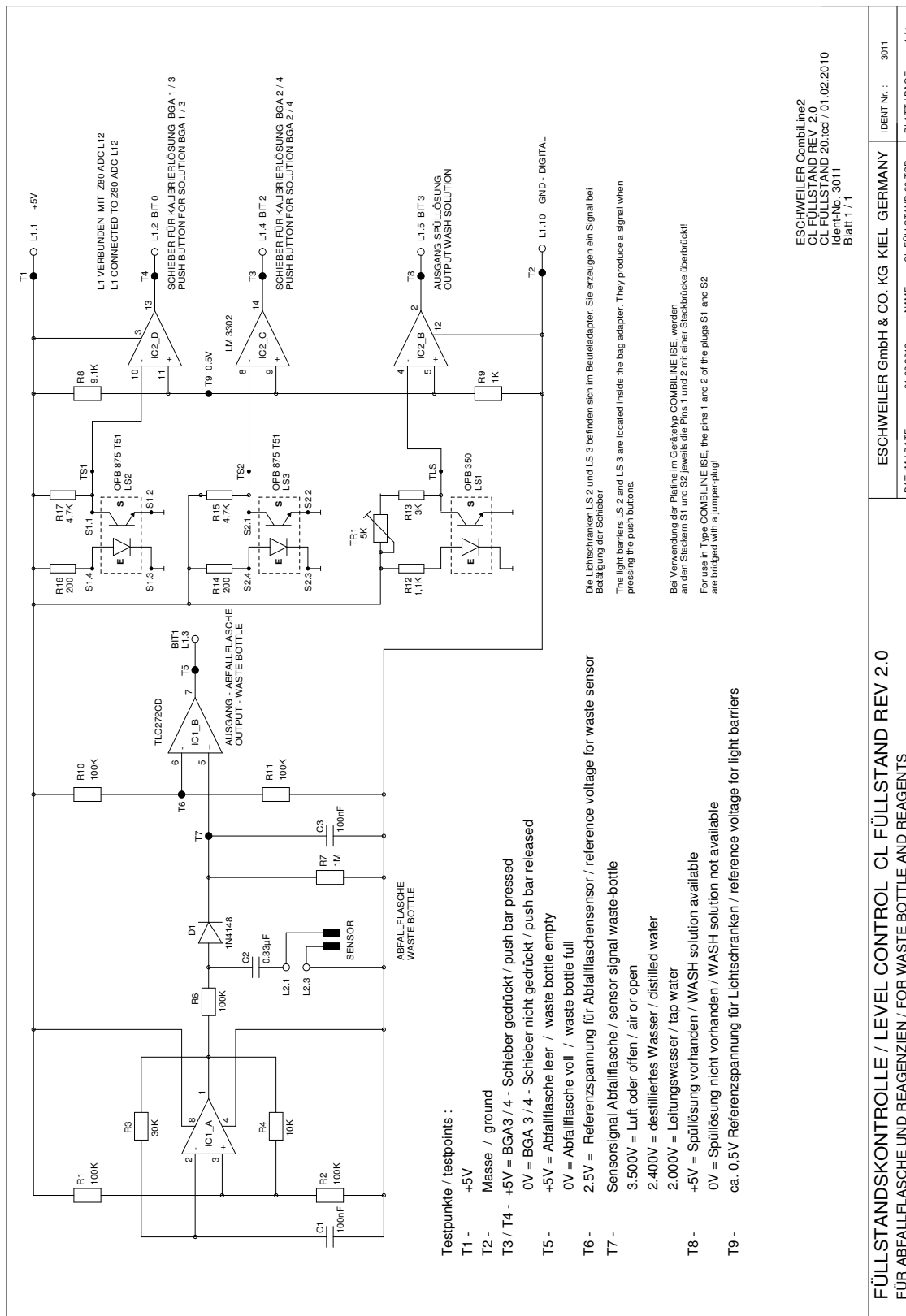
Layout



Filling-Level Control Board CL-FÜLLSTAND

Fill Level Control CL FÜLLSTAND

Circuit Diagram



Keyboard

Specification

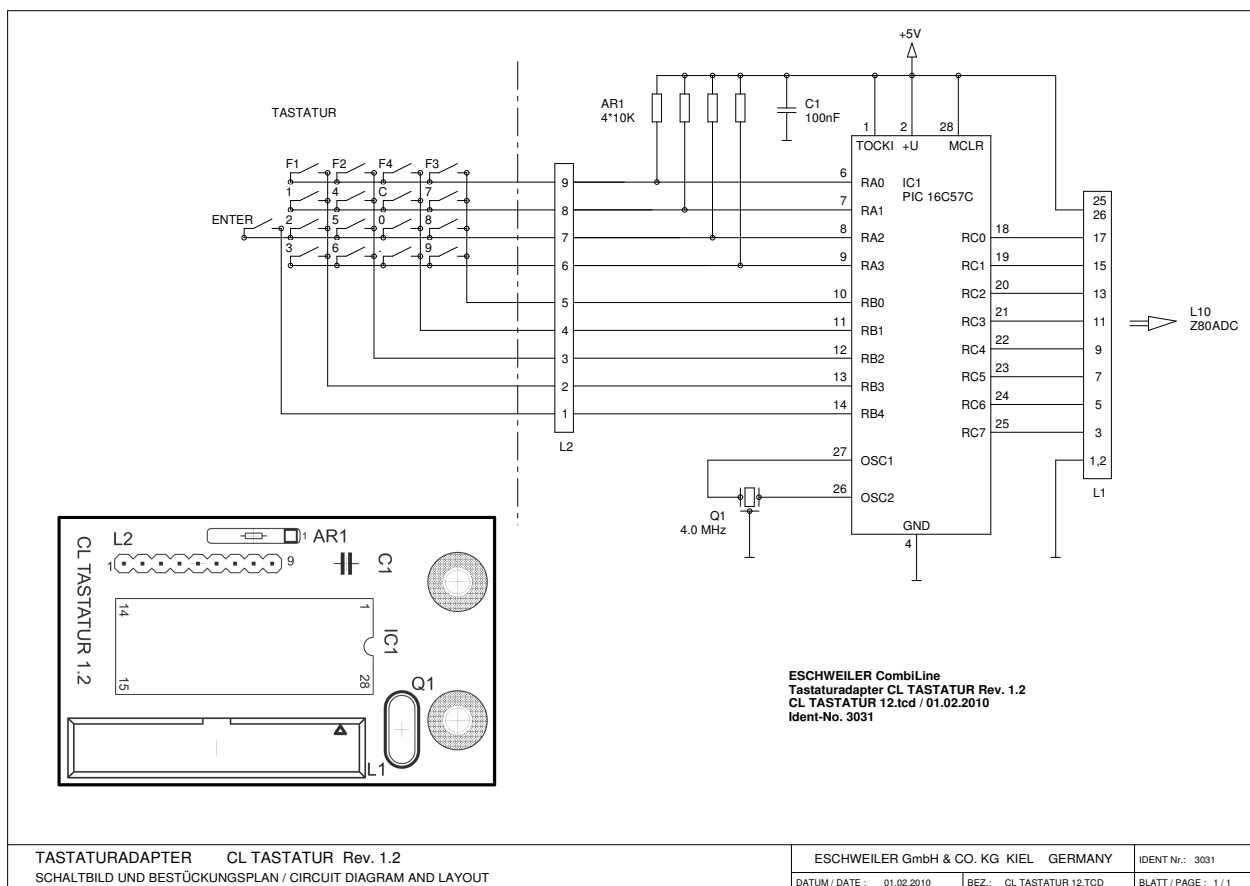
The keyboard is operated directly at a parallel 8-bit port. Debouncing of the contacts takes place by a programmable Controller (PIC)

The PIC scans the keyboard-matrix permanently. If a key is pressed, the corresponding value is sent to the port. By an interrupt the information is interpreted by the analyser software. The corresponding action will be performed then.

Cleaning

Use a suitable cleaning solution as described in chapter **!2 Maintenance and Hygiene** and pay attention to the notes.

Keyboard Adaptor CL-TASTATUR



LCD-Display

Specification

Type: NLC240x128BTGLE

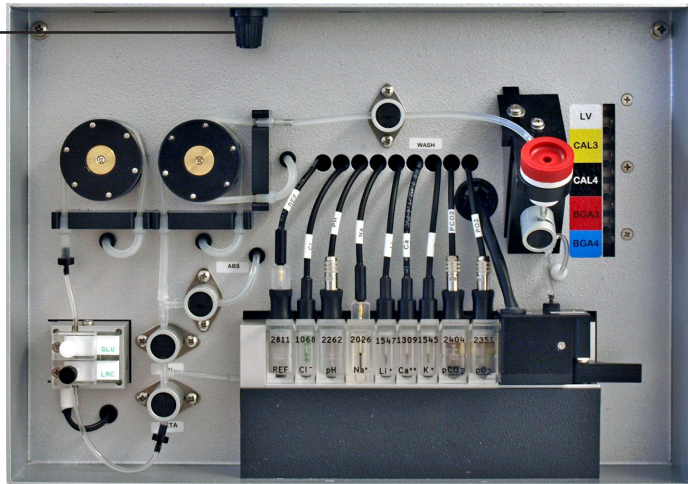
15 lines LCD-Display 30 characters / line

Contrast Adjustment

The trim potentiometer for contrast adjustment is located above the roller pump, as shown in figure 42a.

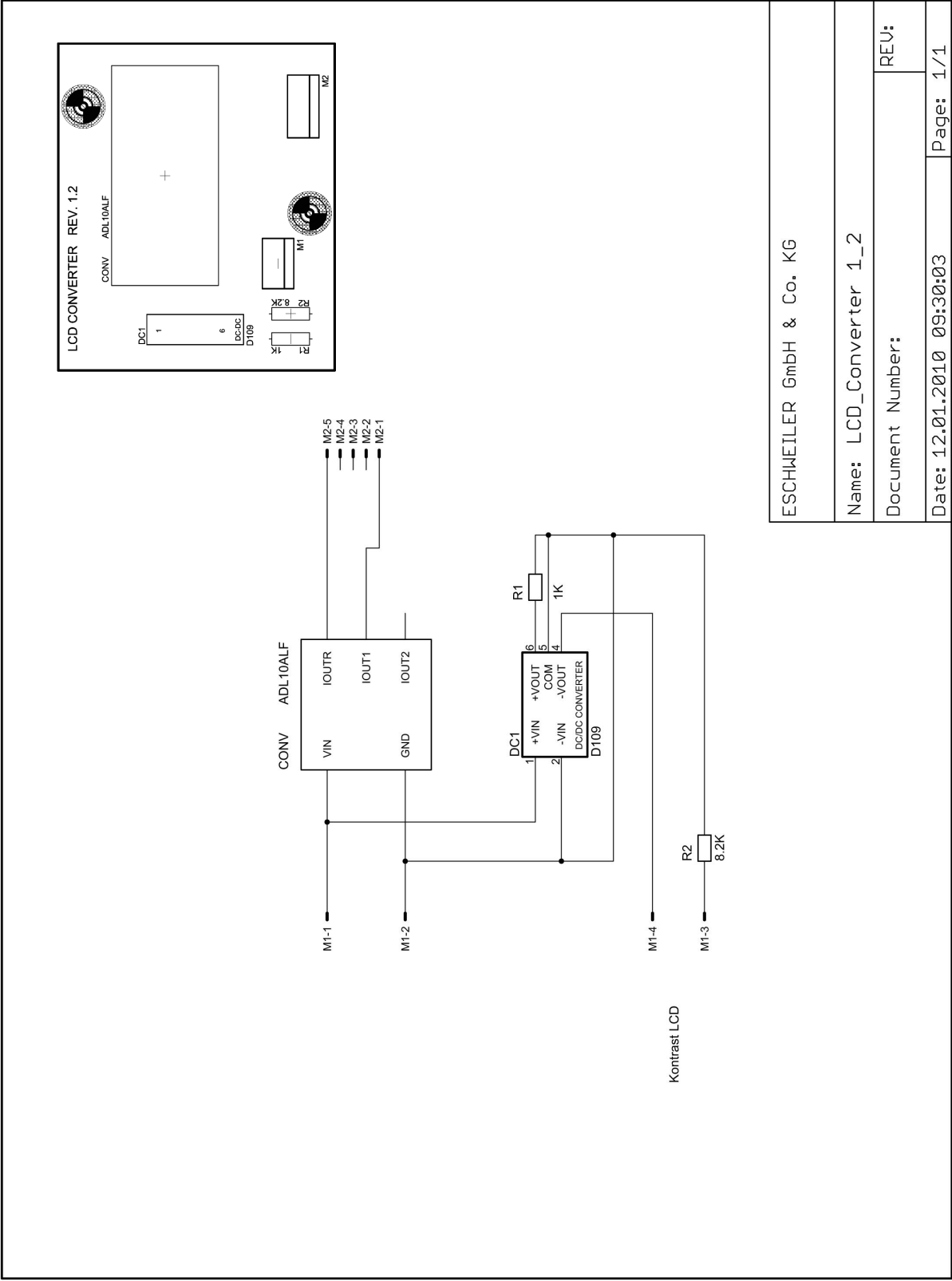
- Turn the potentiometer knob until the contrast of the display is pleasant for the operator.

Contrast Potentiometer for LCD-Display



Display contrast adjustment

Circuit-Diagram and Layout



Pin configuration for Printer GPT-4352-60



Voltage supply plug:

- Pin 1: GND
- Pin 2: GND
- Pin 3: GND
- Pin 4: +24V
- Pin 5: CTS (output)



Figure 44 printer board

Interface (TTL/ 4,5V Pegel):

- Pin 1: GND
- Pin 2: TXD (input)
- Pin 3: RXD (output)
- Pin 4: RTS (input)
- Pin 5: CTS (output)

Paper specifications:

Roll diameter:	up to 60mm
Roll width:	57mm
Paper thickness:	0.04mm



Key-Functions

FEED / ENTER key (1)

Printer self test:

Press key 1 then switch analyser ON.

Keep key 1 pressed for at least 3 seconds.

The printer software version and the character set will be printed

Paper feed will be performed during normal operation

Liquid-Valve SMC

Description

Liquids will be sucked in by the control of Liquid Valves. 5 of them are sampled together to an array back beside of the Sample Port inside the housing. The Liquid Valves are controlled by the NT-Move board.

Following liquids are controlled by the Liquid Valves (depending on configuration)

BGA 1 for Calibration Solution BGA 1
BGA 2 for Calibration Solution BGA 2
BGA 3 for Calibration Solution BGA 3
BGA 4 for Calibration Solution BGA 4
CAL 3 for Calibration solution CAL 3
CAL 4 for Calibration solution CAL 4 (+M)
LV for Air

Sedimentation

After a longer period of use, or the COMBILINE Layout has been parked for a longer time, it can be possible that a sedimentation on the seal can cause a leakage.

Error evidence:

Valve does not respond of commands: Check magnetic coil with a digital multimeter. In case of trouble, replace valve.

In case of sedimentations inside of the valve, the liquid cannot be transported properly. The valve must be cleaned inside.

Replacement of a Liquid Valve

Order no.:

40 8 20 10 Liquid-valve block SMC complete, for COMBILINE BGA+E and meta versions

40 8 20 15 Liquid-valve block SMC complete, for COMBILINE BGA

40 8 20 20 Liquid-valve block SMC complete, for COMBILINE ISE

Order no. of a single valve:

50 8 30 20 Liquid-valve SMC

- Proceed as follows:
- Power OFF COMBILINE and disconnect it from Mains.
- Unscrew the three slotted-head retaining screws at the right side of the reagent wall.
- Remove all tubes from the valves.

Each of the valves is assembled together with two screws.

- Unscrew the two two for dismantling.
- Replace the valve to be replaced.
- Plug in the cables at the new valve (don't misplace cable!)
- Assemble the valve group in reverse order.

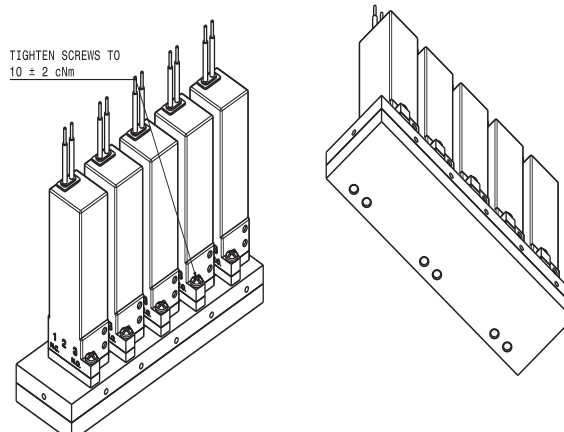
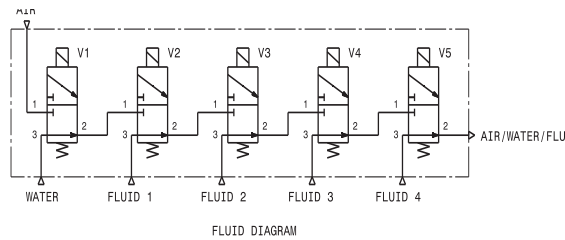
continued next page

- Power ON COMBILINE and open REAGENT TRANSPORT in SERVICE menu
- Ventilate the replaced Valve by pressing the corresponding function-key

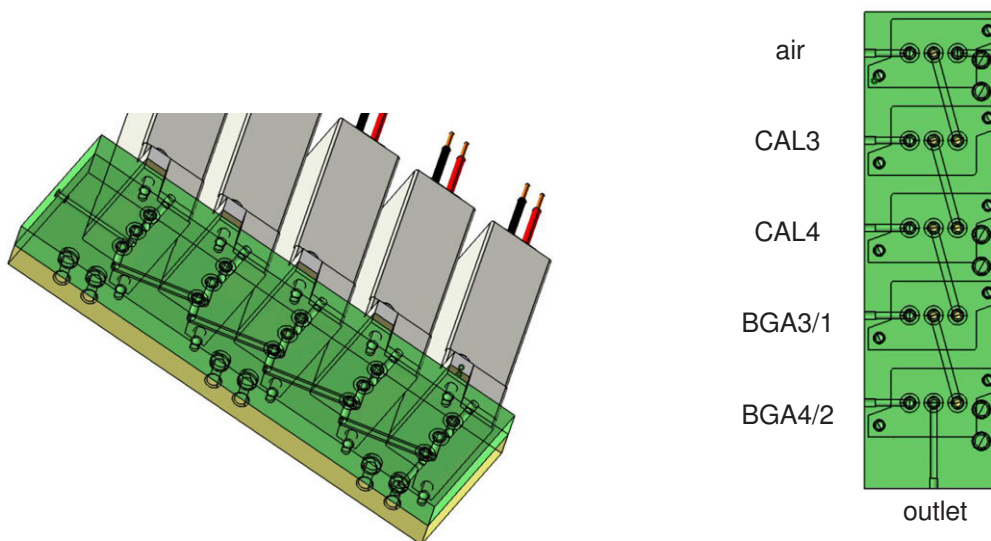
Cleaning of a Liquid Valve

Proceed as described as follows:

- Dismantle the Valve Group.
- Dismantle the Valve as described above
- Clean the internal parts with suitable cleaning solution.
- For assembling of the valve proceed in reverse order.
- For reassembling of the Valve Group proceed as described b



Liquid Valve - SMC Type



Liquid Valve SMC Type - Fluidics

Replacement of the Suction Pump

The Suction Pump is mounted with an aluminium angle beside the transformer and is controlled by the Main Board M1.

For a replacement proceed as follows:

- Switch OFF COMBILINE and disconnect it from Mains.
- Unscrew the two retaining screws on the aluminium angle.
- Remove angle from pump.
- Exchange the two cables to the new motor (don't misplace cables!).
- Exchange the two tubes (don't misplace in/out).
- Assemble the new pump with aluminium angle to its place.
- Switch ON COMBILINE.
- Open the dialogue REAGENTTRANSPORT in SERVICE-TEST menu
- Press 1-key for SUCTION to check its functioning.

Cleaning of Pump's Head

The internal parts of the pump could properly be contaminated with biological material. There is a risk of infection!

- Wear gloves!
- Uninstall the Suction Pump as described in the chapter above.
- Remove lid (B) from pump head, see figure 49 on next page. Liquid-Valve
- Remove the two screws (A) and the front panel (don't loose centre ring for motor axis).
- Loosen the allen screw (D) at motor axis.
- Remove both retaining screws for motor and pull pump head from motor axis.
- Clean the corresponding internal parts with a suitable solution, see chapter !2 Hygiene.

Attention: There is no spare part available!

- Proceed in reverse order to install the pump head.
- Check the functioning as described in the above.

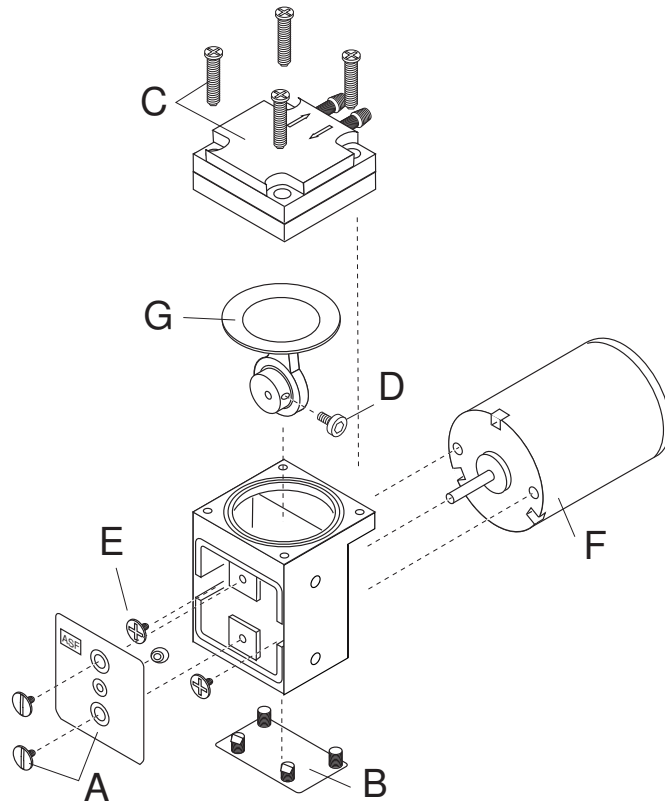
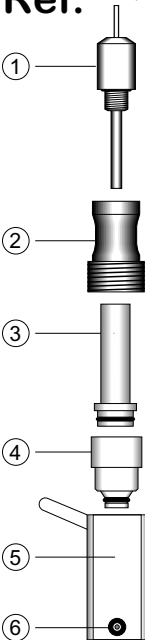
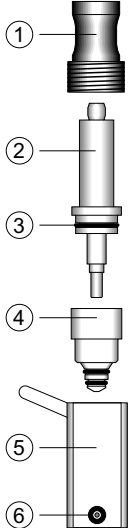
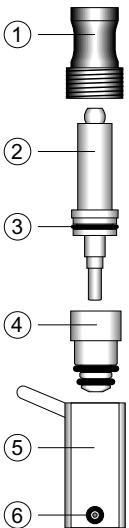
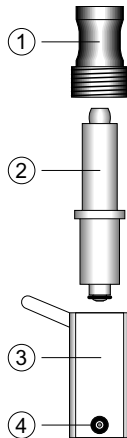


Figure 49 Suction Pump exploded

Sensor Spare Parts

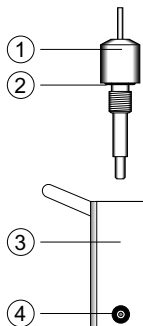
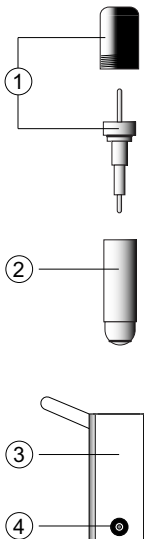
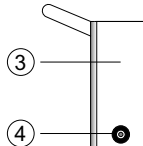
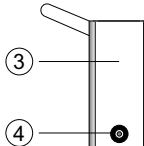
Sensor Spare Parts and average lifetime information

Ref.	Haltbarkeit (Monate) durability (month)	pO ₂	Haltbarkeit (Monate) durability (month)	pCO ₂	Haltbarkeit (Monate) durability (month)	pH	Haltbarkeit (Monate) durability (month)
	12 - 36		∞		∞		∞
	∞	12 - 48		12 - 24		12 - 24	
	12 - 36						
	3 - 6	3 - 6		3			
	12 - 48	12 - 48		12 - 48		12 - 24	
Referenzsensor kompl. reference sensor compl. 50 5 10 00		pO₂ Sensor kompl. pO₂ sensor compl. 50 1 10 00		pCO₂ Sensor kompl. pCO₂ sensor compl. 50 1 20 00		pH Sensor kompl. pH sensor compl. 50 1 30 00	
① Ref. Ableitsystem ref. conduct. system 50 5 10 10		① Schraubkopf screw cap 50 1 10 21		① Schraubkopf screw cap 50 1 10 21		① Schraubkopf screw cap 50 1 10 21	
② Schraubkopf screw cap 50 1 10 21		② Sensoreinheit sensor unit 50 1 10 10		② Sensoreinheit sensor unit 50 1 20 10		② Sensoreinheit sensor unit 50 1 30 10	
③ Ref.-Aufsatz ref.- extension 50 5 10 50		③ O-Ring 8.0 x 1.0 o-ring 8.0 x 1.0 50 1 10 50		③ O-Ring 8.0 x 1.0 o-ring 8.0 x 1.0 50 1 10 15		③ Sensorgehäuse sensor casing 50 1 30 20	
④ Hülse mit Membran membrane shell 50 5 10 30		④ Hülse mit Membran membrane shell 50 1 10 30		④ Hülse mit Membran membrane shell 50 1 20 30		④ O-Ring 1.8 x 1.0 o-ring 1.8 x 1.0 50 1 10 25	
⑤ Sensorgehäuse sensor casing 50 5 10 20		⑤ Sensorgehäuse sensor casing 50 1 10 20		⑤ Sensorgehäuse sensor casing 50 1 20 20			
⑥ O-Ring 1.8 x 1.0 o-ring 1.8 x 1.0 50 1 10 25		⑥ O-Ring 1.8 x 1.0 o-ring 1.8 x 1.0 50 1 10 25		⑥ O-Ring 1.8 x 1.0 o-ring 1.8 x 1.0 50 1 10 25			

BGA_combiline/15012009HEU

Sensor Spare Parts

Sensor Spare Parts and average lifetime information

Na	Haltbarkeit (Monate) durability (month)	ISE	Haltbarkeit (Monate) durability (month)
	12 - 36		12 - 36
	Na ⁺ 12-24		12 - 24
Na⁺ Sensor kompl. Na⁺ sensor compl. 50 3 20 00		ISE Sensoren: ISE sensors: K⁺ / Ca⁺⁺ / Cl⁻ / Li⁺	
①	Ableitsystem conducting system 50 3 20 10	K⁺ Sensor kompl. K⁺ sensor compl. 50 3 10 00	
②	O-Ring 3.2 x 1.8 o-ring 3.2 x 1.8 50 3 20 15	Ca⁺⁺ Sensor kompl. Ca⁺⁺ sensor compl. 50 3 30 00	
③	Na ⁺ Sensorgehäuse Na ⁺ sensor casing 50 3 20 20	Cl⁻ Sensor kompl. Cl⁻ sensor compl. 50 3 40 00	
④	O-Ring 1.8 x 1.0 o-ring 1.8 x 1.0 50 1 10 25	Li⁺ Sensor kompl. Li⁺ sensor compl. 50 3 50 00	
Ersatzteile ISE Sensoren / spare parts ISE sensors K⁺ / Ca⁺⁺ / Cl⁻ / Li⁺			
①	Ableitsystem conducting system K ⁺ 50 3 10 10 Ca ⁺⁺ 50 3 30 10 Cl ⁻ 50 3 40 10 Li ⁺ 50 3 50 10	③	Sensorgehäuse sensor casing K ⁺ 50 3 10 20 Ca ⁺⁺ 50 3 30 20 Cl ⁻ 50 3 40 20 Li ⁺ 50 3 50 20
②	Hülse mit Membran membrane shell K ⁺ 50 3 10 30 Ca ⁺⁺ 50 3 30 30 Cl ⁻ 50 3 40 30 Li ⁺ 50 3 50 30	④	O-Ring 1.8 x 1.0 o-ring 1.8 x 1.0 50 1 10 25

Lifetime of Sensors

Lebensdauer von Sensoren / Lifetime of sensors			
		Ableitsystem conducting system	Membran membrane
Ref.	Referenzsensor reference sensor 50 5 10 00	12 - 36 Monate 12 - 36 months	6 - 9 Monate 6 - 9 months
		Sensor-Einheit sensor unit	Membran membrane
pO ₂	pO ₂ Sensor pO ₂ sensor 50 1 10 00	12 - 48 Monate 12 - 48 months	3 - 6 Monate 3 - 6 months
pCO ₂	pCO ₂ Sensor pCO ₂ sensor 50 1 20 00	12 - 24 Monate 12 - 24 months	3 - 6 Monate 3 - 6 months
pH	pH Sensor pH sensor 50 1 30 00	12 - 24 Monate 12 - 24 months	
		Ableitsystem ^① conducting system ^①	Membran membrane
K ⁺	K ⁺ Sensor K ⁺ sensor 50 3 10 00	12 - 36 Monate 12 - 36 months	3 - 6 Monate 3 - 6 months
Na ⁺	Na ⁺ Sensor Na ⁺ sensor 50 3 20 00	12 - 36 Monate 12 - 36 months	12 - 24 Monate 12 - 24 months
Ca ⁺⁺	Ca ⁺⁺ Sensor Ca ⁺⁺ sensor 50 3 30 00	12 - 36 Monate 12 - 36 months	3 - 6 Monate 3 - 6 months
Cl ⁻	Cl ⁻ Sensor Cl ⁻ sensor 50 3 40 00	12 - 36 Monate 12 - 36 months	3 - 6 Monate 3 - 6 months
Li ⁺	Li ⁺ Sensor Li ⁺ sensor 50 3 50 00	12 - 36 Monate 12 - 36 months	3 - 6 Monate 3 - 6 months
GLU	GLU Sensor GLU sensor 50 4 20 00		30 Tage oder ca. 1000 Proben 30 days or approx. 1000 samples
LAC	LAC Sensor LAC sensor 50 4 10 00		15 Tage oder ca. 400 Proben 15 days or approx. 400 samples
^① Das Ableitsystem der ISE-Sensoren kann bei Beschädigung der Chloridschicht werksseitig regeneriert werden. In case of damaged chlorid layer the conducting system of ISE sensors can be regenerated by manufacturer.			

The lifetimes given in the above table are average lifetimes

List of Consumables

Article no.:	description	packing/unit
Calibration- and Rinsing solutions for combiline BGA		
3-4.100	WASH 1 (Rinsing solution for BGA)	6x330 ml
40 6 10 20	BGA 1 (Calibration solution for BGA / low)	12x130 ml
40 6 10 30	BGA 2 (Calibration solution for BGA / high)	12x130 ml
for combiline BGA+E		
40 6 10 10	WASH 2 (Rinsing solution for BGA plus E)	6x250 ml
40 6 10 40	BGA 3 (Calibration solution BGA plus E/low)	12x130 ml
40 6 10 50	BGA 4 (Calibration solution BGA plus E/high)	12x130 ml
40 6 10 45	CAL 3 (Calibration solution for BGA plus E/low)	12x150 ml
40 6 10 55	CAL 4 (Calibration solution for BGA plus E/high)	12x150 ml
for COMBILINE meta		
40 6 10 11	WASH 2+M Rinsing solution	8x250 ml
40 6 10 40	BGA 3 Calibration solution BGA plus E/low	12x130 ml
40 6 10 50	BGA 4 Calibration solution BGA plus E/high	12x130 ml
40 6 10 45	CAL 3 Calibration solution for BGA plus E/low	12x150 ml
40 6 10 56	CAL 4+M Calibration solution for BGA plus E/high	12x150 ml
for combiline ISE		
3-4.110	WASH 2 (Rinsing solution for ISE)	6x330 ml
3-4.400	CAL 3 (Calibration solution for ISE/low)	6x330 ml
3-4.500	CAL 4 (Calibration solution for ISE/high)	6x330 ml
Special Solutions		
50 6 10 80	Protein remover	1 x 100 ml
50 6 10 84	Electrode cleaner	50 ml
50 6 10 88	Activating solution for pH-sensor	20 ml
Quality Controls		
Control Solutions for BGA		
50 6 20 10	Level I BGA (acidosis)	30 ampoules
50 6 20 20	Level II BGA (normal)	30 ampoules
50 6 20 30	Level III BGA (alkalosis)	30 ampoules
Control Solutions for BGA plus E		
50 6 20 40	Level I BGA+E (acidosis)	30 ampoules
50 6 20 50	Level II BGA+E (normal)	30 ampoules
50 6 20 60	Level III BGA+E (alkalosis)	30 ampoules
50 6 20 70	Level IV (high pO ₂)	30 ampoules
Control Solutions for BGA plus E+Li+		
50 6 20 45	Level I EGL (acidosis)	30 ampoules
50 6 20 55	Level II EGL (normal)	30 ampoules
50 6 20 65	Level III EGL (alkalosis)	30 ampoules
Sampling Systems		
Capillaries		
50 6 30 08	hep. capillaries 8 cm/lg	250 pcs.
50 6 30 10	hep. capillaries 10 cm/lg	250 pcs.
50 6 30 12	hep. capillaries 12 cm/lg	250 pcs.
50 6 30 14	hep. capillaries 14 cm/lg for instruments with Hb sensor	250 pcs.
50 6 30 16	hep. capillaries 16 cm/lg for instr. with meta and Hb sensor	250 pcs.
50 6 30 30	metal stirrers for capillaries	250 pcs.
50 6 30 35	magnet for stirrer	
50 6 30 40	end-caps for capillaries	500 pcs.

List of Consumables

Article no.:	description	packing/unit
Aspiration Pipes		
3-7.200	pipe for control solution, activating solution etc.	10 pcs.
50 6 30 55	ampoule holder for aspiration pipe	1 pc.
Printer Paper		
50 6 50 00	printer paper	pack.=2 rolls
Cleaning Paste		
50 1 10 41	cleaning paste (silicon carbide)	
Accessories for Maintenance		
40 6 40 00	service-set complete for COMBILINE <u>without Metabolites</u>	
consisting of:		
40 6 40 10	set tubings for roller-pump (reagents)	2 pcs.
40 6 40 15	tubing for magnetic valve VE1	1 pc.
40 6 40 20	tubing for magnetic valve VE2	1 pc.
40 6 40 25	tubing for magnetic valve ABS	1 pc.
40 6 40 01	service-set complete for COMBILINE <u>with Metabolites</u>	
consisting of:		
40 6 40 11	set tubings for roller-pump (reagents)	2 pcs.
40 6 40 15	tubing for magnetic valve VE1	1 pc.
40 6 40 20	tubing for magnetic valve VE2	1 pc.
40 6 40 25	tubing for magnetic valve ABS	1 pc.
1-8.106	sample port insert (red)	1 pc.
Sensors		
pO₂-Sensor		
50 1 10 00	pO ₂ -Sensor complete	
50 1 10 10	pO ₂ -Sensor-unit with membrane shell	
50 1 10 15	gasket for Sensor-unit (8.0 x 1.0)	
50 1 10 20	pO ₂ -Sensor-casing with screw-cap	
50 1 10 21	screw cap for Sensor-casing	
50 1 10 25	gasket for Sensor-casing (1.8 x 1.0)	
50 1 10 30	pO ₂ -membrane shells	pack.= 5 pcs.
50 1 10 35	pO ₂ -fill solution	bot.=20 ml
50 1 10 50	polishing kit for pO ₂ sensors	
pCO₂-Sensor		
50 1 20 00	pCO ₂ -Sensor complete	
50 1 20 10	pCO ₂ -Sensor-unit with membrane shell	
50 1 20 15	gasket for Sensor-unit (8.0 x 1.0)	
50 1 20 20	pCO ₂ -Sensor-casing	
50 1 10 21	screw cap for Sensor-casing	
50 1 10 25	gasket for Sensor-casing (1.8 x 1.0)	
50 1 20 30	pCO ₂ -membrane shells	pack.=5 pcs.
50 1 20 35	pCO ₂ -fillsolution	bot.=20 ml
pH-Sensor		
50 1 30 00	pH-Sensor complete	
50 1 30 10	pH-Sensor-unit	
50 1 30 20	pH-Sensor-casing	
50 1 10 21	screw cap for Sensor-casing	
50 1 10 25	gasket for Sensor-casing (1.8 x 1.0)	

List of Consumables

Article no.:	description	packing/unit
Hb-Sensor		
50 2 10 01	Hb-Sensor Type II complete	
K⁺-Sensor		
50 3 10 00	K ⁺ -Sensor complete	
50 3 10 10	K ⁺ -conducting system	
50 3 10 20	K ⁺ -Sensor casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 3 10 30	K ⁺ -membrane shell with membrane	
50 3 10 35	K ⁺ -fillsolution (organic tenside, buffer substances)	bot.=20 ml
Na⁺-Sensor		
50 3 20 00	Na ⁺ -Sensor complete	btl.= bottle
50 3 20 10	Na ⁺ -conducting system	
50 3 20 15	gasket for conducting system (3.2 x 1.8)	
50 3 20 20	Na ⁺ -Sensor-casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 3 20 35	Na ⁺ -fillsolution	bot.= 20 ml
Ca⁺⁺-Sensor		
50 3 30 00	Ca ⁺⁺ -Sensor complete	
50 3 30 10	Ca ⁺⁺ -conducting system	
50 3 30 20	Ca ⁺⁺ -Sensor casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 3 30 30	Ca ⁺⁺ -membrane shell with membrane	
50 3 30 35	Ca ⁺⁺ - fillsolution	bot.=20 ml
Cl⁻-Sensor		
50 3 40 00	Cl ⁻ -Sensor complete	
50 3 40 10	Cl ⁻ - conducting system	
50 3 40 20	Cl ⁻ -Sensor casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 3 40 30	Cl ⁻ -membrane shell with membrane	
50 3 40 35	Cl ⁻ -fillsolution	bot.=20 ml
Li⁺-Sensor		
50 3 50 00	Li ⁺ -Sensor complete	
50 3 50 10	Li ⁺ -conducting system	
50 3 50 20	Li ⁺ -Sensor casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
50 3 50 30	Li ⁺ -membrane shell with membrane	
50 3 50 35	Li ⁺ -fillsolution	bot.=20 ml
Reference-Sensor		
40 5 10 00	reference-sensor complete	
50 5 10 10	reference-conducting system	
50 3 20 15	gasket for conducting system (3.2 x 1.8)	
50 5 10 20	reference-Sensor casing	
50 1 10 25	gasket for Sensor-casing 1.8 x 1.0)	
40 5 10 50	reservoir for reference-Sensor casing	
50 5 10 30	ref.-membrane shell with membrane	
50 5 10 35	reference-fillsolution	bot.=50 ml

List of Spare Parts

Article no.: description

System casing

60 7 10 00	system casing, complete
60 7 10 10	front cover complete, painted, with print

Sensor fixing device / Thermostate

50 7 20 00	sensor fixing device, complete
40 7 10 30	device for specimen input
50 7 20 10	closing mechanism
40 7 10 20	sample Light Barrier COMBILINE
40 7 10 25	capillary for sample light barrier
50 7 20 20	board for thermostate illumination, (LED)
50 7 20 21	panel for thermostate illumination (LED), complete
50 7 20 05	temperature safety switch
50 7 20 90	temperature regulation sensor NTC (for Thermostat or Meta block)

Sensor fixing device for Metabolites

50 7 20 60	thermostate block, for Metabolite sensors, complete
50 7 20 70	fixing screw, white, for GLU-Sensor
50 7 20 75	fixing screw, black, for LAC-Sensor
50 7 20 80	holding device for GLU-Sensor
50 7 20 85	holding device for LAC-Sensor
50 7 20 95	peltier-element for Meta-block

Calibration-bag adapter

40 7 10 35	bag-adapter COMBILINE, complete
	consisting of:
G 40.1	metal-casing
40 7 10 40	slide-bar holder COMBILINE
G 41.3	slide-bar COMBI 1 set
G 40.4	spring for slide-bar 1 set
G 40.5	cannula 1set
40 7 10 36	Suspension for Calibration-Bags

Peristaltic pump

50 7 40 00	peristaltic pump, complete
50 7 40 10	micromotor with gear 97.3:1
50 7 40 20	bush for bearing
50 7 40 30	bearing
50 7 40 40	roller device for peristaltic pump
50 7 40 50	clutch

Reagent-wall

50 7 40 60	tube connector, black
50 7 40 61	tube connector, white, reagent-wall
50 7 40 62	tube connector, white, bottle compartment
50 7 40 70	holder for roller pump tubing, reagents (low)
40 7 40 70	holder for roller pump tubing WASH (high)
40 7 10 50	intermediate vessel
40 7 10 55	holder for intermediate vessel

List of Spare Parts

Article no.: description

Bottles for COMBILINE BGA+E

Rm 100.24	waste-bottle 250ml, empty
Rm 100.30	suction tube for reagent bottle WASH (250ml)
Rm 100.31	suction tube for reagent bottle CAL3/4(+M) (150ml)
R 100.21	screw cap for reagent- WASH- or waste-bottle (150 / 250ml)
60 8 20 80	waste bottle device, complete

Bottles for COMBILINE BGA and COMBILINE ISE

Rm 100.23	waste-bottle 330ml (empty)
Rm 100.21	suction tube for reagent bottle WASH / CAL (330ml)
R 100.20	screw cap for CAL- WASH or waste-bottle (330ml)
60 8 20 70	waste bottle device, complete for 330ml bottle

Sample port

Rm 20.80	sample port device, complete with insert consisting of:
R 20.81 (1-8.105)	sample port insert with integr. Steel canula (white)
R 20.83 (1-8.106)	sample port insert (red)
G 20.51	sample port holder
G 20.52	sample port cover
G 20.53	sample port support

Wiring

SEm 100.21	sensor-cable pO ₂
SEm 200.21	sensor-cable pCO ₂
SEm 300.21	sensor-cable pH
SEm 400.21	sensor-cable Na ⁺
SEm 500.21	sensor-cable K ⁺
SEm 600.21	sensor-cable Ca ⁺⁺
SEm 700.21	sensor-cable Li ⁺
SEm 800.21	sensor-cable Cl ⁻
SEm 900.22	sensor-cable reference

Valves

F 200.25	tube valve (normally open)
F 200.28	sample port valve PV (normally open)
50 8 30 20	liquid Valve SMC
40 8 20 11	liquid-valve block SMC complete for COMBILINE BGA+E
40 8 20 16	liquid-valve block SMC complete for COMBILINE BGA
40 8 20 21	liquid-valve block SMC complete for COMBILINE ISE
40 8 20 25	multilayer valve carrier SMC

List of Spare Parts

Article no.: description

Electronic boards (ESW- ANALOG)

60 8 10 10	analog-board for pO2 -pCO2-pH-baro.pressure, temperature
60 8 10 11	analog-board for pO2 -pCO2-pH-baro-pressure-temperature-Hb
60 8 10 15	analog-board for BGA, BP, K-temperature
60 8 10 20	analog-board for BGA, BP, K-Na-temperature
60 8 10 25	analog-board for BGA, BP, K-Na-Ca-temperature
60 8 10 26	analog-board for BGA, BP, K-Na-Cl-temperature
60 8 10 30	analog-board for BGA, BP, K-Na-Ca-Cl-temperature
60 8 10 35	analog-board for BGA, BP, K-Na-Ca-Cl-Li-temperature
60 8 11 10	analog-board for pO2 -pCO2-pH-Meta-baro.pressure, temperature
60 8 11 11	analog-board for pO2 -pCO2-pH-Meta-baro-pressure-temperature-Hb
60 8 11 15	analog-board for BGA, Meta, BP, K-temperature
60 8 11 20	analog-board for BGA, Meta, BP, K-Na-temperature
60 8 11 25	analog-board for BGA, Meta, BP, K-Na-Ca-temperature
60 8 11 26	analog-board for BGA, Meta, BP, K-Na-Cl-temperature
60 8 11 30	analog-board for BGA, Meta, BP, K-Na-Ca-Cl-temperature
60 8 11 35	analog-board for BGA, Meta, BP, K-Na-Ca-Cl-Li-temperature
60 8 10 40	analog-board for K-Na-temperature
60 8 10 45	analog-board for K-Na-Ca-temperature
60 8 10 50	analog-board for K-Na-Ca-Cl-temperature
60 8 10 55	analog-board for K-Na-Ca-Cl-Li-temperature
40 8 10 60	air pressure sensor 1240-015A-3N
60 8 10 70	CPU board (Z80 ADC)
60 8 10 80	power supply board for valves, motors and temperature regulation (CL TEMP NETZ)
60 8 10 90	switching power supply PM110 45-2A for +5V, -12V, +12V, +24V compl.
40 8 20 00	board for filling level control (CL FÜLLSTAND)
E 210.5	displayadapter (ECODISP)
60 8 20 40	interface RS232 for data output, incl. SD-Card Reader

Various electronical and electrical devices

50 8 20 65	temperature measuring sensor
50 8 20 70	keyboard, complete
50 8 20 71	keyboard adapter CL TASTATUR
F 100.4.2	LCD Display 240x128 dpi
60 8 20 50	LCD Converter
60 8 20 90	thermal printer GBT-4352
F 10.5.1	heating resistor for thermostate heating device
60 8 20 60	fan for power supply 24V, 1W
F 10.19	suction pump



Product Service

CERTIFICATE

No. Z1 10 04 21853 017

Holder of Certificate: Eschweiler GmbH & Co. KGHolzkoppelweg 35
24118 Kiel
GERMANY**Production
Facility(ies):**

21853

Certification Mark:**Product:**

Analysis Equipment

Model(s):combi line meta
combi line**Parameters:**

Rated voltage:	115-230 V
Rated frequency:	50-60Hz
Rated power:	70 W
Protection class:	I

Tested according to:EN 61010-1:2001
EN 61010-2-081/A1:2003
EN 61010-2-101:2002

The product was tested on a voluntary basis and complies with the essential requirements. The certification mark shown above can be affixed on the product. It is not permitted to alter the certification mark in any way. In addition the certification holder must not transfer the certificate to third parties. See also notes overleaf.

Test report no.:

028-71357489-101

Date, 2010-04-12

(Theo Butz)

Page 1 of 1



TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TUV®

ESCHWEILER

■ automatic analysing systems

Eschweiler GmbH & Co. KG • Holzkoppelweg 35 • D - 24118 Kiel

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Declaration of EC-Conformity

as defined by **EC In-Vitro Diagnostica (IVD) directive 98/79/EG**

Eschweiler GmbH & Co. KG
Holzkoppelweg 35 / D-24118 Kiel / Germany

declares that the product

Description: blood gas-/ electrolyte- and metabolite - analysers

Model: **ESCHWEILER combi line**

to which this declaration relates is in accordance with the provisions of the following directives

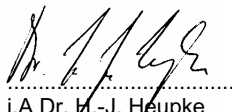
2004/108/EG Electromagnetic Compatibility
2006/95/EG Low Voltage Directive

Applied harmonised standards:

EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use: General requirements
EN 61010-2-08/A1	Safety requirements for electrical equipment for measurement, control, and laboratory use: Particular requirements for laboratory equipment for analysis
EN 61010-2-101	Safety requirements for electrical equipment for measurement, control, and laboratory use: Particular requirements for in vitro diagnostic (IVD) medical equipment
Emission:	
EN 55011 A2	Industrial, scientific and medical radio-frequency equipment – Emission: Class B
EN 61000-3-2	Harmonic current emissions
EN 61000-3-3	Voltage fluctuation and flicker
Immunity:	
EN 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements: Industrial requirement
EN 61000-4-2	Electrostatic discharge immunity test
EN 61000-4-3 +A1	Radiated, radio-frequency electromagnetic field – immunity test
EN 61000-4-4	Electrical fast transient/burst immunity test
EN 61000-4-5	Surge immunity tests
EN 61000-4-6	Immunity to conducted disturbances, induced by radio frequency fields
EN 61000-4-11	Voltage dips, short interruptions and voltage variations immunity test

ESCHWEILER GmbH & Co. KG

Kiel, 01.04.2010


.....
i.A. Dr. H.-J. Heupke
(QCM)



EC declaration combilineV2 IVD engl01012010

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(BLZ 210 400 10)
SWIFT: COBADEFFXXX
IBAN: DE66 2104 0010 0722 4488 00

Postbank
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(BLZ 200 100 20)
SWIFT: PBNKDEFF
IBAN: DE56 2001 0020 0024 6762 04

Gerichtsstand / Place of Jurisdiction: Kiel USt.-ID Nr.: DE 188048227
Handelsregister Kiel HRA 3736 KI Kompl.: Eschweiler Verwaltungs GmbH Kiel HRB 4610 KI Geschäftsführer: Horst H. Kock